

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

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

| Reaction Name | Total | Fatal |
|-----------------------------------------------|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Cerebellar ataxia | 1 | 0 |
| Coordination abnormal | 104 | 0 |
| Dysdiadochokinesis | 1 | 0 |
| Dysstasia | 91 | 0 |
| Hand-eye coordination impaired | 1 | 0 |
| Nystagmus | 19 | 0 |
| Cortical dysfunction NEC | | |
| Agraphia | 1 | 0 |
| Alexia | 4 | 0 |
| Aphasia | 113 | 0 |
| Apraxia | 1 | 0 |
| Dysgraphia | 6 | 0 |
| Dyslexia | 2 | 0 |
| Dyspraxia | 4 | 0 |
| Neurologic neglect syndrome | 3 | 0 |
| Visuospatial deficit | 2 | 0 |
| Cranial nerve disorders NEC | | |
| Cranial nerve disorder | 2 | 0 |
| Cranial nerve paralysis | 1 | 0 |
| Neurovascular conflict | 1 | 0 |
| Paresis cranial nerve | 2 | 0 |
| Dementia (excl Alzheimer's type) | | |
| Dementia | 19 | 0 |
| Dementia with Lewy bodies | 1 | 0 |
| Frontotemporal dementia | 1 | 0 |
| Senile dementia | 1 | 0 |
| Vascular dementia | 4 | 0 |
| Demyelinating disorders NEC | | |
| Acute disseminated encephalomyelitis | 8 | 0 |
| Demyelination | 15 | 0 |
| Neuromyelitis optica spectrum disorder | 1 | 0 |
| Disturbances in consciousness NEC | | |
| Altered state of consciousness | 12 | 0 |
| Consciousness fluctuating | 4 | 0 |
| Depressed level of consciousness | 76 | 0 |
| Lethargy | 4340 | 0 |
| Loss of consciousness | 918 | 0 |
| Postictal state | 1 | 0 |
| Sedation | 12 | 0 |
| Somnolence | 1668 | 1 |
| Stupor | 8 | 0 |
| Syncope | 2199 | 0 |
| Disturbances in sleep phase rhythm | | |
| Advanced sleep phase | 1 | 0 |
| Circadian rhythm sleep disorder | 5 | 0 |
| Delayed sleep phase | 1 | 0 |
| Irregular sleep phase | 1 | 0 |
| Irregular sleep wake rhythm disorder | 1 | 0 |
| Dyskinesias and movement disorders NEC | | |
| Akathisia | 10 | 0 |
| Ballismus | 1 | 0 |
| Bradykinesia | 27 | 0 |
| Clumsiness | 41 | 0 |

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|----------------------------------------------|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Dyskinesia | 96 | 0 |
| Extrapyramidal disorder | 18 | 0 |
| Fine motor delay | 3 | 0 |
| Fine motor skill dysfunction | 11 | 0 |
| Hyperkinesia | 26 | 0 |
| Hypokinesia | 55 | 0 |
| Meige's syndrome | 1 | 0 |
| Motor dysfunction | 13 | 0 |
| Movement disorder | 70 | 0 |
| Psychomotor hyperactivity | 34 | 0 |
| Tardive dyskinesia | 1 | 0 |
| Dystonias | | |
| Dystonia | 17 | 0 |
| Dystonic tremor | 3 | 0 |
| Opisthotonus | 4 | 0 |
| Writer's cramp | 1 | 0 |
| Encephalitis NEC | | |
| Noninfective encephalitis | 4 | 0 |
| Encephalopathies NEC | | |
| Autoimmune encephalopathy | 3 | 0 |
| Encephalopathy | 5 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| Posterior reversible encephalopathy syndrome | 2 | 0 |
| Encephalopathies toxic and metabolic | | |
| Hepatic encephalopathy | 2 | 0 |
| Eye movement disorders | | |
| IIIrd nerve disorder | 1 | 0 |
| IIIrd nerve paralysis | 6 | 0 |
| Microvascular cranial nerve palsy | 2 | 0 |
| VIth nerve paralysis | 8 | 0 |
| Facial cranial nerve disorders | | |
| Bell's palsy | 391 | 0 |
| Facial nerve disorder | 4 | 0 |
| Facial paralysis | 230 | 0 |
| Facial paresis | 120 | 0 |
| Facial spasm | 28 | 0 |
| Oculofacial paralysis | 1 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 71 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 5 | 0 |
| Cluster headache | 632 | 0 |
| Cold-stimulus headache | 70 | 0 |
| Drug withdrawal headache | 15 | 0 |
| Exertional headache | 10 | 0 |
| External compression headache | 4 | 0 |
| Headache | 73776 | 4 |
| Medication overuse headache | 14 | 0 |
| New daily persistent headache | 18 | 0 |
| Occipital neuralgia | 17 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Post-traumatic headache | 3 | 0 |
| Primary cough headache | 2 | 0 |

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

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| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Piriformis syndrome | 2 | 0 |
| Radial nerve palsy | 2 | 0 |
| Sciatic nerve neuropathy | 3 | 0 |
| Ulnar nerve palsy | 1 | 0 |
| Ulnar neuritis | 3 | 0 |
| Ulnar tunnel syndrome | 1 | 0 |
| Motor neurone diseases | | |
| Motor neurone disease | 1 | 0 |
| Multiple sclerosis acute and progressive | | |
| Band sensation | 5 | 0 |
| Multiple sclerosis | 48 | 0 |
| Multiple sclerosis relapse | 43 | 0 |
| Relapsing multiple sclerosis | 1 | 0 |
| Uhthoff's phenomenon | 4 | 0 |
| Muscle tone abnormal | | |
| Hypertonia | 2 | 0 |
| Hypotonia | 32 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 7 | 0 |
| Myelitis (incl infective) | | |
| Myelitis transverse | 63 | 0 |
| Narcolepsy and hypersomnia | | |
| Cataplexy | 1 | 0 |
| Hypersomnia | 169 | 0 |
| Narcolepsy | 14 | 0 |
| Nervous system cysts and polyps | | |
| Pineal gland cyst | 1 | 0 |
| Nervous system disorders NEC | | |
| Brain stem syndrome | 2 | 0 |
| Central nervous system lesion | 1 | 0 |
| Cerebral disorder | 1 | 0 |
| Nervous system disorder | 38 | 0 |
| Neurotoxicity | 1 | 0 |
| Psychomotor skills impaired | 4 | 0 |
| Neurologic visual problems NEC | | |
| Hemianopia | 7 | 0 |
| Hemianopia homonymous | 1 | 0 |
| Tunnel vision | 15 | 0 |
| Neurological signs and symptoms NEC | | |
| Agitation neonatal | 1 | 0 |
| Dizziness | 19657 | 0 |
| Dizziness exertional | 84 | 0 |
| Dizziness postural | 1936 | 1 |
| Drooling | 20 | 0 |
| Exaggerated startle response | 3 | 0 |
| Fontanelle bulging | 3 | 0 |
| Head discomfort | 567 | 0 |
| Hyporesponsive to stimuli | 2 | 0 |
| Inability to crawl | 1 | 0 |
| Infant irritability | 5 | 0 |
| Intracranial hypotension | 2 | 0 |
| Meningism | 2 | 0 |
| Myoclonus | 25 | 0 |

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

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| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Freezing phenomenon | 148 | 0 |
| Parkinson's disease | 15 | 0 |
| Parkinsonism | 10 | 0 |
| Reduced facial expression | 6 | 0 |
| Vascular parkinsonism | 1 | 0 |
| Partial complex seizures | | |
| Dreamy state | 19 | 0 |
| Focal dyscognitive seizures | 6 | 0 |
| Temporal lobe epilepsy | 4 | 0 |
| Partial simple seizures NEC | | |
| Autonomic seizure | 1 | 0 |
| Simple partial seizures | 5 | 0 |
| Peripheral neuropathies NEC | | |
| Autoimmune neuropathy | 2 | 0 |
| Axonal neuropathy | 1 | 0 |
| Ischaemic neuropathy | 1 | 0 |
| Neuralgic amyotrophy | 5 | 0 |
| Neuritis | 10 | 0 |
| Neuropathy peripheral | 157 | 0 |
| Peripheral motor neuropathy | 1 | 0 |
| Peripheral sensorimotor neuropathy | 2 | 0 |
| Peripheral sensory neuropathy | 13 | 0 |
| Polyneuropathy | 10 | 0 |
| Small fibre neuropathy | 2 | 0 |
| Thoracic outlet syndrome | 1 | 0 |
| Seizures and seizure disorders NEC | | |
| Alcoholic seizure | 1 | 0 |
| Atonic seizures | 10 | 0 |
| Change in seizure presentation | 7 | 0 |
| Clonic convulsion | 8 | 0 |
| Drug withdrawal convulsions | 2 | 0 |
| Epilepsy | 246 | 0 |
| Epileptic aura | 2 | 0 |
| Febrile convulsion | 87 | 0 |
| Migraine-triggered seizure | 1 | 0 |
| Myoclonic epilepsy | 4 | 0 |
| Partial seizures | 50 | 0 |
| Psychogenic seizure | 5 | 0 |
| Seizure | 1054 | 2 |
| Seizure anoxic | 3 | 0 |
| Seizure cluster | 6 | 0 |
| Seizure like phenomena | 2 | 0 |
| Status epilepticus | 114 | 3 |
| Tonic clonic movements | 2 | 0 |
| Tonic convulsion | 32 | 0 |
| Sensory abnormalities NEC | | |
| Ageusia | 929 | 0 |
| Allodynia | 55 | 0 |
| Aura | 21 | 0 |
| Central pain syndrome | 2 | 0 |
| Complex regional pain syndrome | 8 | 0 |
| Dysgeusia | 1817 | 0 |
| Electric shock sensation | 78 | 0 |

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| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Hypogeusia | 5 | 0 |
| Intercostal neuralgia | 1 | 0 |
| Loss of proprioception | 3 | 0 |
| Neuralgia | 1051 | 0 |
| Persistent genital arousal disorder | 1 | 0 |
| Phantom limb syndrome | 17 | 0 |
| Post herpetic neuralgia | 10 | 0 |
| Restless arm syndrome | 11 | 0 |
| Restless legs syndrome | 327 | 0 |
| Sensory disturbance | 97 | 0 |
| Sensory loss | 170 | 0 |
| Taste disorder | 446 | 0 |
| Vibratory sense increased | 1 | 0 |
| Visual perseveration | 1 | 0 |
| Sleep disturbances NEC | | |
| Microsleep | 2 | 0 |
| Periodic limb movement disorder | 1 | 0 |
| Sleep deficit | 45 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 317 | 0 |
| Incoherent | 15 | 0 |
| Language disorder | 2 | 0 |
| Muscle tension dysphonia | 1 | 0 |
| Slow speech | 28 | 0 |
| Speech disorder | 70 | 0 |
| Spinal cord and nerve root disorders NEC | | |
| Cauda equina syndrome | 4 | 0 |
| Myelopathy | 3 | 0 |
| Radicular pain | 1 | 0 |
| Radiculitis brachial | 12 | 0 |
| Radiculopathy | 2 | 0 |
| Spinal cord disorder | 3 | 0 |
| Spinal cord oedema | 1 | 0 |
| Structural brain disorders NEC | | |
| Brain injury | 21 | 1 |
| Cerebral mass effect | 5 | 0 |
| Intracranial mass | 3 | 0 |
| White matter lesion | 1 | 0 |
| Transient cerebrovascular events | | |
| Transient ischaemic attack | 365 | 0 |
| Tremor (excl congenital) | | |
| Action tremor | 2 | 0 |
| Asterixis | 1 | 0 |
| Essential tremor | 5 | 0 |
| Head titubation | 15 | 0 |
| Intention tremor | 1 | 0 |
| Postural tremor | 1 | 0 |
| Resting tremor | 5 | 0 |
| Tremor | 9074 | 3 |
| Trigeminal disorders | | |
| Facial neuralgia | 31 | 0 |
| Numb chin syndrome | 2 | 0 |
| Trigeminal nerve disorder | 5 | 0 |

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| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Trigeminal neuralgia | 69 | 0 |
| Trigeminal neuritis | 2 | 0 |
| Trigeminal palsy | 1 | 0 |
| Vagus nerve disorders | | |
| Vagus nerve paralysis | 1 | 0 |
| Vocal cord paralysis | 1 | 0 |
| Vertigos NEC | | |
| Vertigo CNS origin | 2 | 0 |
| Nervous system disorders SOC TOTAL | 154901 | 152 |

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|--------------------------------------------------------------|------------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 80 | 1 |
| <i>Foetal complications NEC</i> | | |
| Foetal disorder | 2 | 0 |
| Foetal hypokinesia | 1 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Face presentation | 2 | 0 |
| <i>High risk pregnancies</i> | | |
| Pregnancy with young maternal age | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Precipitate labour | 1 | 0 |
| Premature labour | 3 | 0 |
| Premature rupture of membranes | 1 | 0 |
| Prolonged labour | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Uterine contractions abnormal | 1 | 0 |
| Uterine hypertonus | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Ectopic pregnancy | 3 | 0 |
| Hyperemesis gravidarum | 2 | 0 |
| Morning sickness | 36 | 0 |
| Pelvic girdle pain | 1 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Labour pain | 1 | 0 |
| Pregnancy | 21 | 0 |
| Uterine contractions during pregnancy | 1 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 5 | 0 |
| <i>Stillbirth and foetal death</i> | | |
| Foetal death | 1 | 0 |
| Stillbirth | 3 | 1 |
| <i>Umbilical cord complications</i> | | |
| Umbilical cord abnormality | 1 | 0 |
| <i>Unintended pregnancies</i> | | |
| Pregnancy after post coital contraception | 3 | 0 |
| Pregnancy on contraceptive | 2 | 0 |
| Pregnancy on oral contraceptive | 1 | 0 |
| Pregnancy with contraceptive device | 1 | 0 |
| Pregnancy with implant contraceptive | 3 | 0 |
| Unintended pregnancy | 5 | 0 |
| Pregnancy conditions SOC TOTAL | 184 | 2 |

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| <i>Device electrical issues</i> | | |
| Device electrical impedance issue | 1 | 0 |
| <i>Device incompatibility issues</i> | | |
| Patient-device incompatibility | 1 | 0 |
| <i>Device issues NEC</i> | | |
| Device issue | 2 | 0 |
| Device leakage | 2 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Oversensing | 24 | 0 |
| Stent malfunction | 1 | 0 |
| Thrombosis in device | 37 | 0 |
| Undersensing | 3 | 0 |
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 7 | 0 |
| Syringe issue | 1 | 0 |
| <i>Manufacturing facilities and equipment issues</i> | | |
| Manufacturing equipment issue | 1 | 0 |
| <i>Product contamination and sterility issues</i> | | |
| Product contamination | 1 | 0 |
| <i>Product distribution and storage issues</i> | | |
| Product temperature excursion issue | 3 | 0 |
| <i>Product label issues</i> | | |
| Product barcode issue | 1 | 0 |
| Product label issue | 2 | 0 |
| <i>Product packaging issues</i> | | |
| Product container issue | 1 | 0 |
| <i>Product physical issues</i> | | |
| Product colour issue | 1 | 0 |
| Product leakage | 1 | 0 |
| Product odour abnormal | 1 | 0 |
| Product physical issue | 1 | 0 |
| Product taste abnormal | 7 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product formulation issue | 1 | 0 |
| Product origin unknown | 2 | 0 |
| Product quality issue | 1 | 0 |
| Suspected product quality issue | 3 | 0 |
| null SOC TOTAL | 106 | 0 |

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| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 15 | 0 |
| Breath holding | 4 | 0 |
| Sexually inappropriate behaviour | 1 | 0 |
| Staring | 9 | 0 |
| <i>Abnormal food elimination</i> | | |
| Self-induced vomiting | 1 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder with depressed mood | 5 | 0 |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 9 | 0 |
| Constricted affect | 5 | 0 |
| Flat affect | 10 | 0 |
| Inappropriate affect | 15 | 0 |
| <i>Amnesic symptoms</i> | | |
| Paramnesia | 4 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Anxiety disorder | 2 | 0 |
| Generalised anxiety disorder | 2 | 0 |
| Neurosis | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 175 | 0 |
| Anxiety | 894 | 0 |
| Immunisation anxiety related reaction | 1 | 0 |
| Nervousness | 543 | 0 |
| Procedural anxiety | 1 | 0 |
| Stress | 96 | 0 |
| Tension | 58 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 13 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 10 | 0 |
| Antisocial behaviour | 1 | 0 |
| Asocial behaviour | 1 | 0 |
| Aversion | 1 | 0 |
| Disinhibition | 1 | 0 |
| Impatience | 2 | 0 |
| Indifference | 8 | 0 |
| Paranoia | 36 | 0 |
| Personality change | 5 | 0 |
| Social avoidant behaviour | 4 | 0 |
| Soliloquy | 3 | 0 |
| Violence-related symptom | 3 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 6 | 0 |
| Bipolar disorder | 3 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Change in sustained attention | 1 | 0 |
| Daydreaming | 13 | 0 |
| Distractibility | 1 | 0 |
| Mental fatigue | 402 | 0 |
| <i>Communications disorders</i> | | |

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

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

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

| Reaction Name | Total | Fatal |
|----------------------------------------------------------------------------|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Acrophobia | 1 | 0 |
| Agoraphobia | 3 | 0 |
| Fear | 34 | 0 |
| Fear of death | 13 | 0 |
| Fear of disease | 2 | 0 |
| Fear of eating | 1 | 0 |
| Fear of falling | 3 | 0 |
| Fear of injection | 2 | 0 |
| Fear of open spaces | 1 | 0 |
| Performance fear | 2 | 0 |
| Phobia | 2 | 0 |
| Phonophobia | 3 | 0 |
| Social fear | 1 | 0 |
| <i>Fluctuating mood symptoms</i> | | |
| Mood swings | 70 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 848 | 0 |
| Hallucination, auditory | 38 | 0 |
| Hallucination, olfactory | 8 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 52 | 0 |
| Hallucinations, mixed | 8 | 0 |
| <i>Impulse control disorders</i> | | |
| Impulse-control disorder | 2 | 0 |
| Impulsive behaviour | 1 | 0 |
| Intermittent explosive disorder | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 440 | 0 |
| <i>Infancy, childhood and adolescence psychiatric disorders NEC</i> | | |
| Emotional disorder of childhood | 1 | 0 |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 12 | 0 |
| Mental status changes | 3 | 0 |
| <i>Mental disorders due to a general medical condition NEC</i> | | |
| Mental disorder due to a general medical condition | 1 | 0 |
| Neuropsychiatric symptoms | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Anhedonia | 3 | 0 |
| Decreased interest | 12 | 0 |
| Depressed mood | 506 | 0 |
| Depressive symptom | 1 | 0 |
| Feeling guilty | 1 | 0 |
| Feeling of despair | 16 | 0 |
| Negative thoughts | 8 | 0 |
| Sense of a foreshortened future | 1 | 0 |
| Tearfulness | 95 | 0 |
| <i>Mood alterations with manic symptoms</i> | | |
| Hypomania | 1 | 0 |
| Mania | 29 | 0 |
| <i>Mood disorders NEC</i> | | |
| Affective disorder | 3 | 0 |
| Apathy | 48 | 0 |

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| Reaction Name | Total | Fatal |
|--------------------------------------------------------------------------|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Laziness | 1 | 0 |
| Listless | 117 | 0 |
| Mood disorder due to a general medical condition | 1 | 0 |
| Substance-induced mood disorder | 1 | 0 |
| <i>Narcolepsy and associated conditions</i> | | |
| Hypnagogic hallucination | 4 | 0 |
| Sleep attacks | 1 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Body dysmorphic disorder | 2 | 0 |
| Compulsive shopping | 2 | 0 |
| Dermatillomania | 1 | 0 |
| Obsessive thoughts | 3 | 0 |
| Obsessive-compulsive disorder | 1 | 0 |
| <i>Orgasmic disorders and disturbances</i> | | |
| Anorgasmia | 3 | 0 |
| Female orgasmic disorder | 1 | 0 |
| Orgasm abnormal | 1 | 0 |
| Orgasmic sensation decreased | 4 | 0 |
| Premature ejaculation | 2 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Limited symptom panic attack | 1 | 0 |
| Panic attack | 253 | 0 |
| Panic disorder | 3 | 0 |
| Panic reaction | 31 | 0 |
| <i>Paraphilias and paraphilic disorders</i> | | |
| Fetishism | 2 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 335 | 0 |
| Abnormal sleep-related event | 1 | 0 |
| Confusional arousal | 2 | 0 |
| Exploding head syndrome | 6 | 0 |
| Nightmare | 412 | 0 |
| Parasomnia | 1 | 0 |
| Rapid eye movements sleep abnormal | 3 | 0 |
| Sleep inertia | 1 | 0 |
| Sleep talking | 16 | 0 |
| Sleep terror | 55 | 0 |
| Sleep-related eating disorder | 2 | 0 |
| Somnambulism | 9 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Autoscopy | 21 | 0 |
| Deja vu | 4 | 0 |
| Delusional perception | 2 | 0 |
| Derealisation | 13 | 0 |
| Flashback | 2 | 0 |
| Illusion | 11 | 0 |
| Pseudohallucination | 1 | 0 |
| Time perception altered | 5 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 3 | 0 |
| <i>Psychiatric elimination disorders</i> | | |
| Enuresis | 45 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--------------------------------------------------------------------------|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Helplessness | 2 | 0 |
| Hypervigilance | 13 | 0 |
| Psychiatric symptom | 7 | 0 |
| Psychological trauma | 3 | 0 |
| Psychotic disorder NEC | | |
| Acute psychosis | 4 | 0 |
| Psychotic behaviour | 2 | 0 |
| Psychotic disorder | 33 | 0 |
| Psychotic symptom | 1 | 0 |
| Rebound psychosis | 1 | 0 |
| Schizoaffective and schizophreniform disorders | | |
| Schizoaffective disorder | 1 | 0 |
| Schizophrenia NEC | | |
| Schizophrenia | 1 | 0 |
| Sexual arousal disorders | | |
| Disturbance in sexual arousal | 3 | 0 |
| Sexual desire disorders | | |
| Hypersexuality | 1 | 0 |
| Libido decreased | 14 | 0 |
| Libido increased | 5 | 0 |
| Loss of libido | 33 | 0 |
| Sexual dysfunction NEC | | |
| Genito-pelvic pain/penetration disorder | 1 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 339 | 0 |
| Sleep disorder due to general medical condition, insomnia type | 2 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 15 | 0 |
| Habit cough | 31 | 0 |
| Illness anxiety disorder | 1 | 0 |
| Psychogenic tremor | 2 | 0 |
| Somatic symptom disorder | 1 | 0 |
| Speech and language usage disturbances | | |
| Disorganised speech | 16 | 0 |
| Logorrhoea | 3 | 0 |
| Pedantic speech | 1 | 0 |
| Poverty of speech | 1 | 0 |
| Verbigeration | 1 | 0 |
| Speech articulation and rhythm disturbances | | |
| Dysphemia | 24 | 0 |
| Lack of spontaneous speech | 2 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 29 | 0 |
| Head banging | 37 | 0 |
| Waxy flexibility | 2 | 0 |
| Stress disorders | | |
| Acute stress disorder | 2 | 0 |
| Burnout syndrome | 11 | 0 |
| Hyperarousal | 3 | 0 |
| Post-traumatic stress disorder | 11 | 0 |
| Substance related and addictive disorders | | |
| Alcohol abuse | 2 | 0 |
| Alcohol use disorder | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--------------------------------------------------------------------------|--------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Alcoholic hangover | 1 | 0 |
| Alcoholism | 3 | 0 |
| Dependence | 2 | 0 |
| Drug abuse | 1 | 0 |
| Drug dependence | 1 | 0 |
| Substance abuse | 1 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Completed suicide | 2 | 2 |
| Intentional self-injury | 8 | 0 |
| Self-injurious ideation | 2 | 0 |
| Suicidal behaviour | 3 | 0 |
| Suicidal ideation | 91 | 0 |
| Suicide attempt | 17 | 0 |
| Suicide threat | 1 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 78 | 0 |
| Confabulation | 1 | 0 |
| Impaired reasoning | 3 | 0 |
| Intrusive thoughts | 3 | 0 |
| Morbid thoughts | 4 | 0 |
| Tachyphrenia | 22 | 0 |
| Thinking abnormal | 23 | 0 |
| Thought blocking | 4 | 0 |
| <i>Tic disorders</i> | | |
| Tic | 9 | 0 |
| Psychiatric disorders SOC TOTAL | 14510 | 3 |

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| Reaction Name | Total | Fatal |
|---------------------------------------------------------|-------|-------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 7 | 0 |
| Bladder irritation | 6 | 0 |
| Bladder pain | 48 | 0 |
| Bladder spasm | 1 | 0 |
| Dysuria | 69 | 0 |
| Incontinence | 66 | 0 |
| Micturition disorder | 3 | 0 |
| Micturition frequency decreased | 1 | 0 |
| Micturition urgency | 93 | 0 |
| Mixed incontinence | 1 | 0 |
| Pollakiuria | 251 | 0 |
| Urethral pain | 4 | 0 |
| Urge incontinence | 2 | 0 |
| Urinary hesitation | 5 | 0 |
| Urinary incontinence | 102 | 0 |
| Urinary retention | 65 | 0 |
| Urine flow decreased | 12 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder dilatation | 1 | 0 |
| Bladder disorder | 15 | 0 |
| Urinary bladder haemorrhage | 8 | 1 |
| <i>Bladder infections and inflammations</i> | | |
| Cystitis haemorrhagic | 1 | 0 |
| Cystitis interstitial | 5 | 0 |
| Cystitis noninfective | 3 | 0 |
| Lupus cystitis | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Urinary tract disorder | 5 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Anti-glomerular basement membrane disease | 1 | 0 |
| Focal segmental glomerulosclerosis | 1 | 0 |
| Glomerulonephritis membranoproliferative | 1 | 0 |
| Glomerulonephritis membranous | 1 | 0 |
| Glomerulonephritis minimal lesion | 3 | 0 |
| Henoch-Schonlein purpura nephritis | 1 | 0 |
| IgA nephropathy | 3 | 0 |
| Nephrotic syndrome | 12 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Automatic bladder | 1 | 0 |
| Bladder dysfunction | 3 | 0 |
| Hypertonic bladder | 13 | 0 |
| Loss of bladder sensation | 11 | 0 |
| Neurogenic bladder | 2 | 0 |
| <i>Nephritis NEC</i> | | |
| Lupus nephritis | 1 | 0 |
| Nephritis | 5 | 0 |
| Tubulointerstitial nephritis | 4 | 0 |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Nephropathy | 2 | 0 |
| <i>Renal disorders NEC</i> | | |
| Oedematous kidney | 1 | 0 |
| Renal disorder | 7 | 0 |

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| Reaction Name | Total | Fatal |
|------------------------------------------------------------------------|-------------|----------|
| Renal & urinary disorders | | |
| Renal & urinary disorders cont'd | | |
| Renal haemorrhage | 1 | 0 |
| Renal failure and impairment | | |
| Acute kidney injury | 46 | 1 |
| Anuria | 5 | 0 |
| Chronic kidney disease | 8 | 0 |
| Oliguria | 10 | 0 |
| Renal failure | 20 | 3 |
| Renal impairment | 12 | 0 |
| Renal injury | 4 | 0 |
| Renal hypertension and related conditions | | |
| Hypertensive nephropathy | 1 | 0 |
| Renal lithiasis | | |
| Nephrolithiasis | 14 | 0 |
| Renal obstructive disorders | | |
| Hydronephrosis | 1 | 0 |
| Renal structural abnormalities and trauma | | |
| Kidney enlargement | 1 | 0 |
| Renal atrophy | 2 | 0 |
| Renal vascular and ischaemic conditions | | |
| Renal artery occlusion | 1 | 0 |
| Renal embolism | 1 | 0 |
| Renal infarct | 10 | 0 |
| Renal tubular injury | 1 | 0 |
| Renal vein embolism | 1 | 0 |
| Renal vein occlusion | 1 | 0 |
| Renal vein thrombosis | 8 | 0 |
| Structural and obstructive urethral disorders (excl congenital) | | |
| Urethral spasm | 1 | 0 |
| Ureteric disorders NEC | | |
| Ureteral disorder | 2 | 0 |
| Urinary abnormalities | | |
| Chromaturia | 89 | 0 |
| Glycosuria | 1 | 0 |
| Haematuria | 52 | 0 |
| Microalbuminuria | 1 | 0 |
| Proteinuria | 7 | 0 |
| Urine abnormality | 17 | 0 |
| Urine odour abnormal | 19 | 0 |
| Urinary tract lithiasis (excl renal) | | |
| Calculus bladder | 1 | 0 |
| Urinary tract signs and symptoms NEC | | |
| Costovertebral angle tenderness | 1 | 0 |
| Haemorrhage urinary tract | 39 | 0 |
| Nocturia | 17 | 0 |
| Polyuria | 29 | 0 |
| Renal colic | 2 | 0 |
| Renal pain | 838 | 0 |
| Urinary tract discomfort | 1 | 0 |
| Urinary tract pain | 12 | 0 |
| Renal & urinary disorders SOC TOTAL | 2125 | 5 |

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| Reaction Name | Total | Fatal |
|---------------------------------------------------------------------|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 7 | 0 |
| <i>Breast disorders NEC</i> | | |
| Breast disorder | 1 | 0 |
| Breast enlargement | 5 | 0 |
| Breast mass | 38 | 0 |
| Gynaecomastia | 7 | 0 |
| Nipple disorder | 1 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Breast inflammation | 2 | 0 |
| Nipple inflammation | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discharge | 8 | 0 |
| Breast discolouration | 1 | 0 |
| Breast discomfort | 8 | 0 |
| Breast engorgement | 5 | 0 |
| Breast haemorrhage | 1 | 0 |
| Breast induration | 1 | 0 |
| Breast oedema | 1 | 0 |
| Breast pain | 343 | 0 |
| Breast swelling | 48 | 0 |
| Breast tenderness | 44 | 0 |
| Nipple exudate bloody | 1 | 0 |
| Nipple pain | 30 | 0 |
| Nipple swelling | 2 | 0 |
| <i>Cervix disorders NEC</i> | | |
| Cervix haemorrhage uterine | 1 | 0 |
| Ectropion of cervix | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Ejaculation delayed | 1 | 0 |
| Ejaculation disorder | 3 | 0 |
| Ejaculation failure | 2 | 0 |
| Erectile dysfunction | 53 | 0 |
| Erection increased | 4 | 0 |
| Organic erectile dysfunction | 17 | 0 |
| Painful erection | 1 | 0 |
| Priapism | 3 | 0 |
| Retrograde ejaculation | 2 | 0 |
| Spontaneous penile erection | 2 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 1 | 0 |
| <i>Lactation disorders</i> | | |
| Galactorrhoea | 2 | 0 |
| Lactation disorder | 2 | 0 |
| Lactation puerperal increased | 3 | 0 |
| Suppressed lactation | 21 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Artificial menopause | 2 | 0 |
| Menopausal disorder | 2 | 0 |
| Menopausal symptoms | 26 | 0 |
| Menopause delayed | 3 | 0 |
| Premature menopause | 8 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |

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| Reaction Name | Total | Fatal |
|-------------------------------------------------------------|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Postmenopausal haemorrhage | 155 | 0 |
| Menstruation and uterine bleeding NEC | | |
| Abnormal uterine bleeding | 4 | 0 |
| Abnormal withdrawal bleeding | 4 | 0 |
| Dysmenorrhoea | 325 | 0 |
| Intermenstrual bleeding | 236 | 0 |
| Menstrual discomfort | 3 | 0 |
| Menstrual disorder | 461 | 0 |
| Menstruation irregular | 603 | 0 |
| Premenstrual headache | 2 | 0 |
| Premenstrual pain | 21 | 0 |
| Premenstrual syndrome | 10 | 0 |
| Retrograde menstruation | 1 | 0 |
| Withdrawal bleed | 9 | 0 |
| Menstruation with decreased bleeding | | |
| Amenorrhoea | 166 | 0 |
| Hypomenorrhoea | 141 | 0 |
| Menstruation delayed | 792 | 0 |
| Oligomenorrhoea | 32 | 0 |
| Menstruation with increased bleeding | | |
| Heavy menstrual bleeding | 1309 | 0 |
| Menometrorrhagia | 7 | 0 |
| Polymenorrhoea | 182 | 0 |
| Ovarian and fallopian tube cysts and neoplasms | | |
| Ovarian cyst | 10 | 0 |
| Ovarian cyst ruptured | 1 | 0 |
| Polycystic ovaries | 13 | 0 |
| Ovarian and fallopian tube disorders NEC | | |
| Fallopian tube spasm | 1 | 0 |
| Ovarian enlargement | 1 | 0 |
| Ovarian haemorrhage | 3 | 0 |
| Ovarian necrosis | 1 | 0 |
| Ovarian oedema | 1 | 0 |
| Ovarian vein thrombosis | 2 | 0 |
| Ovulation pain | 14 | 0 |
| Premature ovulation | 2 | 0 |
| Pelvic prolapse conditions | | |
| Vaginal prolapse | 1 | 0 |
| Pelvis and broad ligament disorders NEC | | |
| Adnexa uteri pain | 23 | 0 |
| Pelvic haematoma | 1 | 0 |
| Pelvic haemorrhage | 10 | 0 |
| Penile and scrotal infections and inflammations | | |
| Balanoposthitis | 2 | 0 |
| Penile disorders NEC (excl erection and ejaculation) | | |
| Penile blister | 6 | 0 |
| Penile burning sensation | 1 | 0 |
| Penile curvature | 2 | 0 |
| Penile discharge | 2 | 0 |
| Penile exfoliation | 1 | 0 |
| Penile haemorrhage | 4 | 0 |
| Penile oedema | 3 | 0 |
| Penile pain | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--------------------------------------------------------------------------|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Penile size reduced | 1 | 0 |
| Penis disorder | 6 | 0 |
| Peyronie's disease | 4 | 0 |
| <i>Prostate and seminal vesicles infections and inflammations</i> | | |
| Prostatitis | 4 | 0 |
| <i>Prostatic neoplasms and hypertrophy</i> | | |
| Benign prostatic hyperplasia | 2 | 0 |
| <i>Prostatic signs, symptoms and disorders NEC</i> | | |
| Prostatism | 1 | 0 |
| Prostatomegaly | 3 | 0 |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Female genital tract fistula | 1 | 0 |
| Genital blister | 3 | 0 |
| Genital haemorrhage | 14 | 0 |
| Genital hyperaesthesia | 1 | 0 |
| Genital hypoaesthesia | 2 | 0 |
| Genital lesion | 1 | 0 |
| Genital paraesthesia | 2 | 0 |
| Genital ulceration | 12 | 0 |
| Perineal disorder | 2 | 0 |
| <i>Reproductive tract infections and inflammations NEC</i> | | |
| Genital tract inflammation | 2 | 0 |
| <i>Reproductive tract neoplasms NEC</i> | | |
| Genital cyst | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital burning sensation | 7 | 0 |
| Genital discomfort | 3 | 0 |
| Genital erythema | 1 | 0 |
| Genital pain | 3 | 0 |
| Genital rash | 2 | 0 |
| Pelvic discomfort | 2 | 0 |
| Pelvic pain | 114 | 0 |
| Perineal pain | 1 | 0 |
| Pruritus genital | 6 | 0 |
| <i>Scrotal disorders NEC</i> | | |
| Scrotal dermatitis | 1 | 0 |
| Scrotal oedema | 1 | 0 |
| Scrotal pain | 11 | 0 |
| Scrotal swelling | 5 | 0 |
| Varicocele | 1 | 0 |
| <i>Sexual function and fertility disorders NEC</i> | | |
| Dyspareunia | 3 | 0 |
| Female sexual dysfunction | 1 | 0 |
| Infertility | 1 | 0 |
| Infertility female | 1 | 0 |
| Infertility male | 2 | 0 |
| Male sexual dysfunction | 1 | 0 |
| Sexual dysfunction | 7 | 0 |
| <i>Spermatogenesis and semen disorders</i> | | |
| Aspermia | 1 | 0 |
| Haemospermia | 7 | 0 |
| Semen discolouration | 2 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--------------------------------------------------------|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Testicular atrophy | 1 | 0 |
| Testicular disorder | 5 | 0 |
| Testicular mass | 1 | 0 |
| Testicular oedema | 2 | 0 |
| Testicular pain | 88 | 0 |
| Testicular retraction | 1 | 0 |
| Testicular swelling | 13 | 0 |
| Testis discomfort | 3 | 0 |
| Testicular and epididymal neoplasms | | |
| Epididymal cyst | 1 | 0 |
| Testicular cyst | 1 | 0 |
| Uterine disorders NEC | | |
| Adenomyosis | 4 | 0 |
| Endometriosis | 35 | 0 |
| Metrorrhoea | 1 | 0 |
| Uterine enlargement | 1 | 0 |
| Uterine haemorrhage | 34 | 0 |
| Uterine pain | 6 | 0 |
| Uterine neoplasms | | |
| Uterine cyst | 1 | 0 |
| Uterine polyp | 3 | 0 |
| Uterine tone disorders | | |
| Uterine spasm | 11 | 0 |
| Vaginal and vulval infections and inflammations | | |
| Vulvovaginal inflammation | 2 | 0 |
| Vulvovaginal cysts and neoplasms | | |
| Bartholin's cyst | 1 | 0 |
| Vaginal cyst | 10 | 0 |
| Vulva cyst | 1 | 0 |
| Vulvovaginal disorders NEC | | |
| Vaginal disorder | 1 | 0 |
| Vaginal haemorrhage | 556 | 0 |
| Vaginal ulceration | 6 | 0 |
| Vulval disorder | 2 | 0 |
| Vulval haemorrhage | 16 | 0 |
| Vulval ulceration | 4 | 0 |
| Vulvovaginal ulceration | 2 | 0 |
| Vulvovaginal signs and symptoms | | |
| Clitoral engorgement | 1 | 0 |
| Enlarged clitoris | 1 | 0 |
| Labia enlarged | 2 | 0 |
| Vaginal discharge | 43 | 0 |
| Vaginal lesion | 4 | 0 |
| Vaginal odour | 1 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal burning sensation | 7 | 0 |
| Vulvovaginal discomfort | 7 | 0 |
| Vulvovaginal dryness | 5 | 0 |
| Vulvovaginal erythema | 1 | 0 |
| Vulvovaginal pain | 24 | 0 |
| Vulvovaginal pruritus | 7 | 0 |
| Vulvovaginal rash | 2 | 0 |
| Vulvovaginal swelling | 5 | 0 |

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

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| Reaction Name | Total | Fatal |
|------------------------------------------------------------------------------------------|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 12 | 0 |
| Apnoeic attack | 1 | 0 |
| Dyspnoea | 5910 | 5 |
| Dyspnoea at rest | 14 | 0 |
| Dyspnoea exertional | 36 | 0 |
| Dyspnoea paroxysmal nocturnal | 1 | 0 |
| Grunting | 2 | 0 |
| Hyperventilation | 84 | 0 |
| Hypopnoea | 196 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 22 | 0 |
| Mouth breathing | 7 | 0 |
| Orthopnoea | 3 | 0 |
| Respiration abnormal | 87 | 0 |
| Respiratory arrest | 19 | 0 |
| Respiratory distress | 9 | 0 |
| Respiratory fatigue | 6 | 0 |
| Sleep apnoea syndrome | 26 | 0 |
| Tachypnoea | 34 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchiectasis | 15 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Aspirin-exacerbated respiratory disease | 1 | 0 |
| Asthma | 490 | 0 |
| Asthma exercise induced | 1 | 0 |
| Asthma late onset | 2 | 0 |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | 2 | 0 |
| Asthmatic crisis | 5 | 0 |
| Bronchitis chronic | 1 | 0 |
| Bronchospasm | 16 | 0 |
| Chronic obstructive pulmonary disease | 31 | 2 |
| Cough variant asthma | 6 | 0 |
| Obstructive airways disorder | 2 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 520 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 2 | 0 |
| Hypercapnia | 1 | 0 |
| Hypoxia | 59 | 1 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 8 | 0 |
| Cough | 3354 | 0 |
| Haemoptysis | 102 | 0 |
| Productive cough | 160 | 0 |
| Sputum discoloured | 9 | 0 |
| Sputum increased | 1 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Reflux laryngitis | 2 | 0 |
| Vocal cord thickening | 2 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Laryngeal oedema | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

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

| Reaction Name | Total | Fatal |
|-------------------------------------------------------------------------------|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Laryngospasm | 2 | 0 |
| Stridor | 19 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 2 | 0 |
| Eosinophilic pneumonia | 1 | 0 |
| Pneumonia aspiration | 22 | 4 |
| Pneumonitis | 21 | 1 |
| Pulmonary sarcoidosis | 2 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 39 | 0 |
| Lower respiratory tract congestion | 4 | 0 |
| Lung opacity | 5 | 0 |
| Pleuritic pain | 31 | 0 |
| Pulmonary haemorrhage | 5 | 1 |
| Pulmonary pain | 186 | 0 |
| Rales | 2 | 0 |
| <i>Mediastinal disorders</i> | | |
| Pulmonary hilum mass | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 414 | 0 |
| Nasal inflammation | 8 | 0 |
| Rhinitis allergic | 22 | 0 |
| Rhinitis perennial | 1 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 1825 | 0 |
| Intranasal hyposaesthesia | 1 | 0 |
| Nasal crusting | 6 | 0 |
| Nasal cyst | 2 | 0 |
| Nasal disorder | 5 | 0 |
| Nasal dryness | 56 | 0 |
| Nasal mucosal discolouration | 1 | 0 |
| Nasal odour | 2 | 0 |
| Nasal oedema | 11 | 0 |
| Nasal polyps | 1 | 0 |
| Nasal pruritus | 8 | 0 |
| Nasal septum deviation | 1 | 0 |
| Nasal septum perforation | 1 | 0 |
| Nasal ulcer | 3 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Cyanosis neonatal | 1 | 0 |
| Gasping syndrome | 2 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Paranasal sinus haemorrhage | 5 | 0 |
| Paranasal sinus hypersecretion | 1 | 0 |
| Paranasal sinus inflammation | 2 | 0 |
| Sinonasal obstruction | 9 | 0 |
| Sinus congestion | 75 | 0 |
| Sinus disorder | 12 | 0 |
| Sinus polyp | 1 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Atelectasis | 4 | 0 |
| Emphysema | 2 | 0 |
| Idiopathic pulmonary fibrosis | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

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

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

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

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

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

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|-------------------------------------------------------|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Scar pain | 11 | 0 |
| Sensitive skin | 538 | 0 |
| Skin burning sensation | 501 | 0 |
| Skin discolouration | 143 | 0 |
| Skin discomfort | 5 | 0 |
| Skin disorder | 22 | 0 |
| Skin fissures | 11 | 0 |
| Skin fragility | 1 | 0 |
| Skin indentation | 14 | 0 |
| Skin induration | 14 | 0 |
| Skin laxity | 1 | 0 |
| Skin lesion | 38 | 0 |
| Skin necrosis | 5 | 0 |
| Skin odour abnormal | 45 | 0 |
| Skin plaque | 3 | 0 |
| Skin reaction | 226 | 0 |
| Skin sensitisation | 83 | 0 |
| Skin swelling | 81 | 0 |
| Skin texture abnormal | 1 | 0 |
| Skin tightness | 29 | 0 |
| Skin warm | 529 | 0 |
| Skin weeping | 5 | 0 |
| Sticky skin | 7 | 0 |
| Target skin lesion | 1 | 0 |
| Transient acantholytic dermatosis | 1 | 0 |
| Yellow skin | 25 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Autoimmune dermatitis | 1 | 0 |
| Dermatitis | 156 | 0 |
| Dermatitis allergic | 262 | 0 |
| Dermatitis atopic | 19 | 0 |
| Dermatitis contact | 17 | 0 |
| Dermatitis diaper | 2 | 0 |
| Dyshidrotic eczema | 7 | 0 |
| Eczema | 221 | 0 |
| Eczema asteatotic | 13 | 0 |
| Eczema nummular | 3 | 0 |
| Eczema weeping | 2 | 0 |
| Hand dermatitis | 5 | 0 |
| Intertrigo | 2 | 0 |
| Perioral dermatitis | 4 | 0 |
| Prurigo | 1 | 0 |
| Rebound eczema | 1 | 0 |
| Seborrhoeic dermatitis | 7 | 0 |
| Skin irritation | 116 | 0 |
| Stasis dermatitis | 3 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 30 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 13 | 0 |
| Fixed eruption | 4 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 2 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 3024 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|-------------------------------------------------------------------------------|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Erythema ab igne | 1 | 0 |
| Palmar erythema | 5 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative | 2 | 0 |
| Dermatitis exfoliative generalised | 6 | 0 |
| Exfoliative rash | 13 | 0 |
| Skin exfoliation | 114 | 0 |
| <i>Granulomatous and deep cutaneous inflammatory conditions</i> | | |
| Granuloma annulare | 3 | 0 |
| <i>Hyperkeratoses</i> | | |
| Hyperkeratosis | 1 | 0 |
| <i>Hyperpigmentation disorders</i> | | |
| Melanoderma | 2 | 0 |
| Skin hyperpigmentation | 6 | 0 |
| Solar lentigo | 5 | 0 |
| <i>Hypertrichoses</i> | | |
| Hypertrichosis | 1 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Skin depigmentation | 7 | 0 |
| Skin hypopigmentation | 1 | 0 |
| Vitiligo | 13 | 0 |
| <i>Lipodystrophies</i> | | |
| Lipoatrophy | 2 | 0 |
| Lipohypertrophy | 2 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Ingrowing nail | 1 | 0 |
| Nail bed disorder | 2 | 0 |
| Nail bed tenderness | 1 | 0 |
| Nail discolouration | 9 | 0 |
| Nail disorder | 1 | 0 |
| Nail growth abnormal | 1 | 0 |
| Nail hypertrophy | 1 | 0 |
| Nail necrosis | 1 | 0 |
| Nail pigmentation | 1 | 0 |
| Nail pitting | 1 | 0 |
| Nail ridging | 6 | 0 |
| Onychalgia | 4 | 0 |
| Onychoclasia | 8 | 0 |
| Onycholysis | 1 | 0 |
| Onychomadesis | 1 | 0 |
| Splinter haemorrhages | 2 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 25 | 0 |
| Panniculitis | 3 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Erythema annulare | 2 | 0 |
| Lichen planus | 20 | 0 |
| Lichen sclerosus | 3 | 0 |
| Parapsoriasis | 1 | 0 |
| Pityriasis rosea | 39 | 0 |
| Pityriasis rubra pilaris | 2 | 0 |
| <i>Photosensitivity and photodermatitis conditions</i> | | |
| Photodermatitis | 2 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

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

Case Series Drug Analysis Print

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

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|-----------------------------------------------------------------------|-------|-------|
| Social circumstances | | |
| <i>Age related issues</i> | | |
| Childhood | 1 | 0 |
| Menarche | 2 | 0 |
| Menopause | 20 | 0 |
| Postmenopause | 5 | 0 |
| <i>Bereavement issues</i> | | |
| Death of relative | 1 | 1 |
| <i>Criminal activity</i> | | |
| Chemical submission | 1 | 0 |
| <i>Dependents</i> | | |
| Sick relative | 1 | 0 |
| <i>Dietary and nutritional issues</i> | | |
| Inadequate diet | 1 | 0 |
| Kosher diet | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 69 | 0 |
| Breast prosthesis user | 2 | 0 |
| Dependence on oxygen therapy | 1 | 0 |
| Disability | 3 | 0 |
| Hearing aid user | 2 | 0 |
| Hearing disability | 1 | 0 |
| Housebound | 2 | 0 |
| Immobile | 39 | 0 |
| Immobilisation prolonged | 3 | 0 |
| Impaired driving ability | 4 | 0 |
| Impaired work ability | 17 | 0 |
| Loss of personal independence in daily activities | 4 | 0 |
| Sight disability | 16 | 0 |
| Sitting disability | 2 | 0 |
| Walking disability | 2 | 0 |
| <i>Educational issues</i> | | |
| Illiteracy | 2 | 0 |
| <i>Employment issues</i> | | |
| Job dissatisfaction | 1 | 0 |
| Retirement | 5 | 0 |
| Stress at work | 1 | 0 |
| <i>Family and partner issues</i> | | |
| Homosexual parent | 1 | 0 |
| <i>Non-occupational and unspecified environmental problems</i> | | |
| Food contamination | 1 | 0 |
| Water pollution | 3 | 0 |
| <i>Pregnancy related circumstances</i> | | |
| Breast feeding | 6 | 0 |
| <i>Sexuality issues</i> | | |
| Anal sex | 1 | 0 |
| Homosexuality | 1 | 0 |
| <i>Social issues NEC</i> | | |
| Blood donor | 2 | 0 |
| Contraindication to medical treatment | 1 | 0 |
| Contraindication to vaccination | 2 | 0 |
| Convalescent | 1 | 0 |
| Hair dye user | 1 | 0 |
| Impaired quality of life | 1 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|------------------------------------------------------------------------|------------|----------|
| Social circumstances <small>Social circumstances cont'd</small> | | |
| Refusal of vaccination | 1 | 0 |
| Tattoo | 1 | 0 |
| <i>Tobacco use</i> | | |
| Non-tobacco user | 3 | 0 |
| Tobacco user | 2 | 0 |
| Social circumstances SOC TOTAL | 237 | 1 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

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

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

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MedDRA Version: MedDRA 24.0

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

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| Reaction Name | Total | Fatal |
|------------------------------------------------------|------------|----------|
| Surgical & medical procedures | | |
| Surgical & medical procedures cont'd | | |
| Dermal filler injection | 1 | 0 |
| Skin lesion excisions | | |
| Tattoo excision | 1 | 0 |
| Small intestine therapeutic procedures | | |
| Ileostomy | 2 | 0 |
| Spine and spinal cord therapeutic procedures | | |
| Spinal operation | 1 | 0 |
| Testicular and scrotal therapeutic procedures | | |
| Testes exploration | 1 | 0 |
| Therapeutic procedures NEC | | |
| Anaphylaxis treatment | 3 | 0 |
| Antiallergic therapy | 1 | 0 |
| Bed rest | 19 | 0 |
| Catheter management | 4 | 0 |
| Catheter placement | 1 | 0 |
| Fatigue management | 1 | 0 |
| Heat therapy | 2 | 0 |
| Hospitalisation | 20 | 0 |
| Immobilisation bandage | 1 | 0 |
| Injection | 35 | 0 |
| Interchange of vaccine products | 2 | 0 |
| Localised alternating hot and cold therapy | 5 | 0 |
| Manipulation | 1 | 0 |
| Mass excision | 10 | 0 |
| Medication dilution | 1 | 0 |
| Physical fitness training | 2 | 0 |
| Product used for unknown indication | 2 | 0 |
| Promotion of wound healing | 1 | 0 |
| Self-medication | 1 | 0 |
| Smoking cessation therapy | 1 | 0 |
| Specialist consultation | 1 | 0 |
| Stoma care | 1 | 0 |
| Therapeutic hypothermia | 2 | 0 |
| Therapy change | 1 | 0 |
| Transgender operation | 1 | 0 |
| Tumour excision | 1 | 0 |
| Tracheal therapeutic procedures | | |
| Tracheostomy | 1 | 0 |
| Uterine therapeutic procedures | | |
| Endometrial ablation | 1 | 0 |
| Hysterectomy | 1 | 0 |
| Vascular therapeutic procedures NEC | | |
| Thrombectomy | 2 | 0 |
| Thrombolysis | 2 | 0 |
| Venous therapeutic procedures | | |
| Phlebotomy | 2 | 0 |
| Surgical & medical procedures SOC TOTAL | 561 | 1 |

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| Reaction Name | Total | Fatal |
|-----------------------------------------------------------|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Accelerated hypertension | 1 | 0 |
| Hypertensive crisis | 10 | 0 |
| Hypertensive emergency | 2 | 0 |
| Hypertensive urgency | 2 | 0 |
| Malignant hypertension | 2 | 0 |
| Tyramine reaction | 1 | 0 |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 9 | 2 |
| Aneurysm ruptured | 1 | 0 |
| Artery dissection | 1 | 0 |
| Venous aneurysm | 1 | 0 |
| <i>Aortic aneurysms and dissections</i> | | |
| Acute aortic syndrome | 1 | 0 |
| Aortic aneurysm | 5 | 0 |
| Aortic dissection | 2 | 1 |
| Aortic intramural haematoma | 1 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 20 | 1 |
| Aortic thrombosis | 11 | 2 |
| <i>Aortic infections and inflammations</i> | | |
| Aortitis | 2 | 0 |
| <i>Aortic necrosis and vascular insufficiency</i> | | |
| Aortic occlusion | 1 | 0 |
| Aortic stenosis | 2 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 4 | 0 |
| Giant cell arteritis | 45 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 18 | 0 |
| Labile blood pressure | 2 | 0 |
| <i>Bruising, ecchymosis and purpura</i> | | |
| Achenbach syndrome | 6 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 98 | 1 |
| Distributive shock | 2 | 0 |
| Hypoperfusion | 2 | 0 |
| Hypovolaemic shock | 1 | 0 |
| Neurogenic shock | 10 | 0 |
| Peripheral circulatory failure | 3 | 0 |
| Shock | 48 | 1 |
| Shock symptom | 5 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Bloody discharge | 10 | 0 |
| Haematoma | 83 | 0 |
| Haemorrhage | 668 | 2 |
| Internal haemorrhage | 21 | 0 |
| Venous haemorrhage | 7 | 0 |
| <i>Lymphangiopathies</i> | | |
| Lymphorrhoea | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 53 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |

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| Reaction Name | Total | Fatal |
|-------------------------------------------------------------------------|-------|-------|
| Vascular disorders Vascular disorders cont'd | | |
| Arterial thrombosis | 22 | 1 |
| Atheroembolism | 1 | 0 |
| Embolism | 244 | 3 |
| Embolism arterial | 3 | 0 |
| Embolism venous | 12 | 1 |
| Microembolism | 3 | 0 |
| Paradoxical embolism | 1 | 0 |
| Thrombophlebitis migrans | 1 | 0 |
| Thrombosis | 1191 | 23 |
| Venous thrombosis | 28 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Arterial occlusive disease | 11 | 0 |
| Arterial spasm | 2 | 0 |
| Arterial stenosis | 1 | 0 |
| Arteriosclerosis | 4 | 0 |
| Infarction | 9 | 0 |
| Ischaemia | 11 | 0 |
| Peripheral venous disease | 5 | 0 |
| Vascular compression | 1 | 0 |
| Vascular occlusion | 1 | 0 |
| Vasospasm | 8 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Angiopathy | 2 | 0 |
| Arterial rupture | 1 | 0 |
| Capillary fragility | 9 | 0 |
| Collateral circulation | 1 | 0 |
| Haemodynamic instability | 2 | 0 |
| Hyperaemia | 2 | 0 |
| Neovascularisation | 1 | 0 |
| Superficial vein prominence | 4 | 0 |
| Vascular pain | 97 | 0 |
| Vascular rupture | 1 | 0 |
| Vascular wall discolouration | 1 | 0 |
| Vasodilatation | 86 | 0 |
| Vein collapse | 1 | 0 |
| Vein discolouration | 5 | 0 |
| Vein disorder | 14 | 0 |
| Vein rupture | 13 | 0 |
| <i>Peripheral aneurysms and dissections</i> | | |
| Peripheral artery aneurysm | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Blue toe syndrome | 32 | 0 |
| Deep vein thrombosis | 880 | 7 |
| Femoral artery embolism | 2 | 0 |
| Iliac artery embolism | 2 | 0 |
| Jugular vein thrombosis | 19 | 0 |
| Pelvic venous thrombosis | 14 | 1 |
| Peripheral artery thrombosis | 15 | 0 |
| Peripheral embolism | 9 | 0 |
| Peripheral vein thrombus extension | 1 | 0 |
| Subclavian artery thrombosis | 1 | 0 |
| Subclavian vein thrombosis | 1 | 0 |
| Thrombophlebitis | 97 | 0 |

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

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