

FOI 21/1222 AstraZeneca Vaccine Analysis Print

All UK spontaneous reports with a Jersey postal code (JE1-5) received up to 01/12/21 for COVID-19 vaccine 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: FOI 21/1222 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Dec-2021

Data Lock Date: 28-Nov-2021 18:30:04

Earliest Reaction Date: 27-Mar-2020

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	4	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
Cardiac disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	3	0
<i>Hearing losses</i>		
Deafness neurosensory	1	0
Deafness unilateral	1	0
Hypoacusis	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	1	0
Ear disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	2	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
<i>Ocular disorders NEC</i>		
Eye pain	4	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye inflammation	1	0
Eye irritation	1	0
Eye pruritus	2	0
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	1	0
<i>Refractive and accommodative disorders</i>		
Myopia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal infarction	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal tear	1	0
<i>Retinopathies NEC</i>		
Retinal exudates	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Halo vision	1	0
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness unilateral	1	0
Eye disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Crohn's disease	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	8	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	3	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	39	0
Vomiting	6	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	2	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	2	0
Gastrointestinal disorders SOC TOTAL	71	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	8	0
Chronic fatigue syndrome	1	0
Fatigue	50	0
Malaise	16	0
<i>Febrile disorders</i>		
Pyrexia	49	0
<i>Feelings and sensations NEC</i>		
Chills	36	0
Feeling abnormal	5	0
Feeling cold	5	0
Feeling hot	2	0
Feeling of body temperature change	3	0
Hangover	1	0
Thirst	4	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
General physical health deterioration	1	1
Illness	2	0
Influenza like illness	8	0
Peripheral swelling	7	0
Swelling	1	0
Swelling face	2	0
<i>Implant and catheter site reactions</i>		
Implant site pain	1	0
<i>Injection site reactions</i>		
Injection site inflammation	1	0
Injection site mass	3	0
Injection site pain	9	0
Injection site rash	1	0
Injection site reaction	1	0
Injection site swelling	1	0
<i>Interactions</i>		
Drug interaction	1	0
<i>Oedema NEC</i>		
Oedema	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	2	0
Chest pain	4	0
Discomfort	1	0
Pain	20	0
Tenderness	2	0
<i>Vaccination site reactions</i>		
Vaccination site discomfort	1	0
Vaccination site erythema	3	0
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site mass	3	0
Vaccination site pain	5	0
Vaccination site pruritus	1	0
Vaccination site swelling	2	0
General disorders SOC TOTAL	269	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	3	0
<i>Immune and associated conditions NEC</i>		
Sensitisation	1	0
Immune system disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Infections		
<i>Coronavirus infections</i>		
COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	1	0
<i>Influenza viral infections</i>		
Influenza	7	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
Rhinitis	2	0
Sinusitis	3	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Viral rash	1	0
Infections SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Injuries		
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Skin procedural complications</i>		
Dermal filler overcorrection	1	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury	1	0
<i>Thermal burns</i>		
Thermal burn	1	0
Injuries SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Blood pH increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time prolonged	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	1	0
Heart rate decreased	1	0
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature fluctuation	1	0
Body temperature increased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	2	0
Investigations SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	6	0
Food craving	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
Pain in jaw	2	0
Spinal pain	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	26	0
Joint stiffness	2	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	39	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	2	0
Muscle spasms	3	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	5	0
Limb discomfort	4	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Neck pain	1	0
Pain in extremity	12	0
<i>Tendon disorders</i>		
Tendon disorder	1	0
Muscle & tissue disorders SOC TOTAL	117	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	3	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	2	0
Loss of consciousness	1	0
Somnolence	1	0
Syncope	4	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Cluster headache	3	0
Cold-stimulus headache	2	0
Headache	73	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Migraine headaches</i>		
Migraine	9	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	19	0
Dizziness postural	2	0
Head discomfort	1	0
<i>Olfactory nerve disorders</i>		
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Dysaesthesia	1	0
Hypoaesthesia	6	0
Paraesthesia	9	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Seizure	2	0
<i>Sensory abnormalities NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Ageusia	1	0
Allodynia	1	0
Neuralgia	4	0
Taste disorder	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	1	0
<i>Tremor (excl congenital)</i>		
Tremor	3	0
Nervous system disorders SOC TOTAL	170	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	2	0
Nervousness	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	3	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Emotional and mood disturbances NEC</i>		
Euphoric mood	1	0
Irritability	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
Hallucinations, mixed	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Psychiatric disorders SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
Renal & urinary disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast discolouration	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	2	0
Menstrual disorder	1	0
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	2	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	5	0
Polymenorrhoea	1	0
Reproductive & breast disorders SOC TOTAL	13	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	7	0
Dyspnoea exertional	1	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Wheezing	5	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	3	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	3	0
Nasal dryness	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Sinus pain	3	0
Respiratory disorders SOC TOTAL	32	0

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Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	4	0
Miliaria	1	0
Night sweats	2	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Sticky skin	1	0
<i>Erythemas</i>		
Erythema	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychalgia	1	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	8	0
Rash erythematous	1	0
Rash macular	2	0
Rash pruritic	2	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Urticarias</i>		
Urticaria	3	0
Skin disorders SOC TOTAL	42	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Sight disability	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	2	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	2	0
<i>Peripheral embolism and thrombosis</i>		
Superficial vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	5	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	19	0
TOTAL REACTIONS FOR DRUG	873	1
TOTAL REPORTS	233	
TOTAL FATAL OUTCOME REPORTS		1