Case Series Drug Analysis Print Name: FOI 22 472 - Bolton - AstraZeneca COVID-19 Vaccine

Report Run Date: 09-Mar-2022

Data Lock Date: 08-Mar-2022 18:30:04

All UK spontaneous reports received up to and including 23/02/2022 for AstraZeneca COVID-19 vaccine where the reporter has concurrently provided a postal code that is located within Bolton.

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.

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymph node pain	2	0
Lymphadenopathy	5	0
Spleen disorders		
Splenomegaly	1	0
Blood disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	11	0
Noninfectious pericarditis		
Pericarditis	4	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Rate and rhythm disorders NEC		
Cardiac flutter	1	0
Tachycardia	7	0
Supraventricular arrhythmias		
Atrial flutter	1	0
Cardiac disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	ı o
Ear pain	9	0
Hearing losses		
Deafness	1	1 0
Sudden hearing loss	1	ı o
Hyperacusia		
Hyperacusis	3	3 0
Inner ear signs and symptoms		
Motion sickness	1	ı o
Tinnitus	8	3 0
Vertigo	4	1 0
Ear disorders SOC TOTAL	28	3 0

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Reaction Name	Total	Fatal
Eye disorders		
Lid, lash and lacrimal structural disorders		
Lagophthalmos	1	0
Ocular bleeding and vascular disorders NEC		
Eye haemorrhage	1	0
Ocular disorders NEC		
Eye pain	7	0
Eye swelling	1	0
Ocular discomfort	1	0
Periorbital swelling	1	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	1	0
Ocular sensation disorders		
Asthenopia	1	0
Photophobia	4	0
Visual disorders NEC		
Photopsia	1	0
Vision blurred	7	0
Visual impairment and blindness (excl colour blindness)		
Blindness transient	1	0
Visual impairment	2	0
Eye disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Colitis (excl infective)		
Colitis ulcerative	1	0
Crohn's disease	1	0
Diarrhoea (excl infective)		
Diarrhoea	29	0
Diarrhoea haemorrhagic	2	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Flatulence	2	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	1	0
Gastritis (excl infective)		
Gastritis	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	12	0
Abdominal pain lower	1	0
Abdominal pain upper	11	0
Gastrointestinal pain	2	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	6	0
Abdominal symptom	1	0
Breath odour	1	0
Dysphagia	1	0
Intestinal haemorrhages	_	_
Rectal haemorrhage	2	0
Nausea and vomiting symptoms		
Nausea	101	0
Retching	1	0
Vomiting	43	0
Non-site specific gastrointestinal haemorrhages		0
Upper gastrointestinal haemorrhage	1	0
Oral dryness and saliva altered	2	0
Dry mouth	3	0
Oral soft tissue disorders NEC	4	^
Lip blister	1	0
Oral soft tissue signs and symptoms	4	0
Oral pain Paraesthesia oral	1	0
	4	0
Oral soft tissue swelling and oedema Lip swelling	1	0
Mouth swelling	1	0
Stomatitis and ulceration		U
Mouth ulceration	3	0
Stomatitis	1	0
Tongue disorders		J
Tongue ulceration	1	0
Tongue signs and symptoms		U
Swollen tongue	2	0
Owolien tongue		U

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Gastrointestinal disorders SOC TOTAL	245	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain	1	0
Asthenic conditions		
Asthenia	14	0
Fatigue	137	0
Malaise	43	0
Death and sudden death		
Death	1	1
Febrile disorders		
Pyrexia	143	0
Feelings and sensations NEC		
Chills	116	0
Feeling abnormal	7	0
Feeling cold	16	0
Feeling hot	8	0
Feeling of body temperature change	1	0
Hangover	1	0
Hunger	1	0
Temperature intolerance	2	0
Thirst	2	0
Gait disturbances		
Gait disturbance	1	0
General signs and symptoms NEC		
Condition aggravated	2	0
Crying	1	0
General symptom	1	0
Illness	13	0
Influenza like illness	25	0
Local reaction	2	0
Peripheral swelling	20	0
Swelling	7	0
Swelling face	2	0
Inflammations		
Inflammation	4	0
Injection site reactions		
Injection site erythema	3	0
Injection site mass	4	0
Injection site pain	13	0
Injection site paraesthesia	1	0
Injection site pruritus	1	0
Injection site scab	1	0
Injection site urticaria	1	0
Injection site warmth	1	0
Pain and discomfort NEC		
Axillary pain	2	0
Chest discomfort	3	0
Chest pain	19	0
Pain	46	0
Tenderness	4	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Drug intolerance	1	0
Inadequate analgesia	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Vaccination site bruising	1	0
Vaccination site erythema	2	0
Vaccination site mass	1	0
Vaccination site movement impairment	1	0
Vaccination site pain	3	0
Vaccination site rash	1	0
Vaccination site swelling	3	0
Vaccination site warmth	2	0
Withdrawal and rebound effects		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	689	1

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Reaction Name	Total	Fatal
Hepatic disorders		
Gallbladder disorders NEC		
Gallbladder polyp	1	0
Hepatic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Atopic disorders		
Seasonal allergy	1	0
Immune system disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Bacterial infection	1	0
Cellulitis	1	0
Central nervous system and spinal infections		
Central nervous system infection	1	0
Coronavirus infections		
COVID-19	11	0
Ear infections		
Labyrinthitis	1	0
Epstein-Barr viral infections		
Infectious mononucleosis	2	0
Eye and eyelid infections		
Eye infection	1	0
Herpes viral infections		
Herpes simplex	1	0
Herpes zoster	5	0
Oral herpes	4	0
Varicella	2	0
Infections NEC		
Infection	1	0
Influenza viral infections		
Influenza	21	0
Upper respiratory tract infections		
Nasopharyngitis	5	0
Sinusitis	1	0
Viral infections NEC		
Sweating fever	2	0
Infections SOC TOTAL	60	0

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Reaction Name	Total	Fatal
Injuries		
Atmospheric pressure injuries		
Hypobarism	1	0
Bone and joint injuries NEC		
Synovial rupture	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	5	0
Nerve injuries NEC		
Nerve injury	1	0
Non-site specific procedural complications		
Injection related reaction	2	0
Site specific injuries NEC		
Limb injury	3	0
Skin injuries NEC		
Contusion	6	0
Thermal burns		
Thermal burn	2	0
Injuries SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Investigations		
Autoimmunity analyses		
Antinuclear antibody positive	1	0
Coagulation and bleeding analyses		
Bleeding time prolonged	1	0
Heart rate and pulse investigations		
Heart rate	3	0
Heart rate increased	10	0
Liver function analyses		
Liver function test abnormal	2	0
Physical examination procedures and organ system status		
Body temperature	3	0
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature increased	3	0
Weight decreased	1	0
Platelet analyses		
Platelet count decreased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure measurement	1	0
Virus identification and serology		
Human papilloma virus test negative	1	0
White blood cell analyses		
White blood cell count	1	0
Investigations SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	17	0
Salt craving	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	1	0
General nutritional disorders NEC		
Abnormal loss of weight	1	0
Iron deficiencies		
Iron deficiency	2	0
Total fluid volume decreased		
Dehydration	3	0
Metabolic disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	2	0
Bone related signs and symptoms		
Bone pain	4	0
Pain in jaw	1	0
Bursal disorders		
Bursitis	1	0
Cartilage disorders		
Costochondritis	1	0
Connective tissue disorders NEC		
Polymyalgia rheumatica	2	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	1	0
Joint related disorders NEC		
Joint lock	1	0
Periarthritis	2	0
Joint related signs and symptoms		
Arthralgia	65	0
Joint stiffness	2	0
Joint swelling	5	0
Joint warmth	1	0
Muscle pains		
Myalgia	62	0
Myofascial pain syndrome	1	0
Muscle related signs and symptoms NEC		
Muscle fatigue	1	0
Muscle spasms	11	0
Muscle twitching	2	0
Muscle weakness conditions		
Muscular weakness	4	0
Musculoskeletal and connective tissue conditions NEC Mobility decreased	2	0
Musculoskeletal stiffness	10	0
Musculoskeletal and connective tissue deformities of skull, face and	10	U
buccal cavity		_
Facial asymmetry	1	0
Musculoskeletal and connective tissue infections and inflammations NEC	4	_
Connective tissue inflammation	1	0
Musculoskeletal and connective tissue pain and discomfort	4.4	_
Back pain	14	0
Growing pains	1	0
Limb discomfort	/	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	12	0
Pain in extremity	61	0
Rheumatic disorder	1	0
Soft tissue disorders NEC		
Groin pain	1	C
Soft tissue swelling	1	C
Tendon disorders		
Tenosynovitis stenosans	1	C
Muscle & tissue disorders SOC TOTAL	284	C

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral haemorrhage	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	3	0
Ischaemic stroke	1	1
Coordination and balance disturbances		
Balance disorder	1	0
Coordination abnormal	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	1	0
Lethargy	16	0
Loss of consciousness	5	0
Sedation	1	0
Somnolence	7	0
Syncope	7	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Headaches NEC		
Cluster headache	4	0
Headache	210	0
Sinus headache	4	0
Tension headache	2	0
Memory loss (excl dementia)		
Amnesia	3	0
Memory impairment	2	0
Mental impairment (excl dementia and memory loss)	_	_
Disturbance in attention	3	0
Migraine headaches	4	
Basilar migraine	1	0
Migraine	28	0
Migraine with aura	2	0
Ophthalmic migraine	1 3	0
Status migrainosus	3	0
Mononeuropathies		_
Peroneal nerve palsy	1	0
Piriformis syndrome	1	0
Myelitis (incl infective)	4	^
Myelitis transverse	ı	0
Neurological signs and symptoms NEC	68	0
Dizziness Dizziness exertional	00	0
	15	0
Dizziness postural Head discomfort		0
Neurological symptom	2	0
1	2	0
Presyncope Officetory person disperdent		U
Olfactory nerve disorders	4	^
Anosmia	1 2	0
Parosmia Parosethesias and diversethesias		U
Paraesthesias and dysaesthesias	4	^
Burning sensation	4	0
Hypoaesthesia	25	0

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Paraesthesia	40	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Partial seizures	1	0
Seizure	10	1
Tonic clonic movements	1	0
Sensory abnormalities NEC		
Ageusia	1	0
Complex regional pain syndrome	1	0
Dysgeusia	9	0
Electric shock sensation	2	0
Neuralgia	5	0
Restless legs syndrome	2	0
Taste disorder	1	0
Speech and language abnormalities		
Slow speech	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Head titubation	1	0
Tremor	34	0
Trigeminal disorders		
Trigeminal nerve disorder	1	0
Nervous system disorders SOC TOTAL	549	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
Normal pregnancy, labour and delivery		
Pregnancy	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	1	0
Pregnancy conditions SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Device malfunction events NEC		
Thrombosis in device	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Affect alterations NEC		
Constricted affect	1	0
Anxiety symptoms		
Anxiety	3	0
Nervousness	4	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	1	0
Confusion and disorientation		
Confusional state	8	0
Disorientation	3	0
Depressive disorders		
Depression	3	0
Depression suicidal	1	0
Major depression	1	0
Dissociative states		
Depersonalisation/derealisation disorder	1	0
Dissociation	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	7	0
Dyssomnias		
Poor quality sleep	2	0
Emotional and mood disturbances NEC		
Emotional disorder	1	0
Emotional distress	1	0
Frustration tolerance decreased	1	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear	2	0
Hallucinations (excl sleep-related)		
Hallucination	4	0
Increased physical activity levels		
Restlessness	1	0
Mood alterations with depressive symptoms		
Depressed mood	4	0
Obsessive-compulsive disorders and symptoms		
Compulsive shopping	1	0
Obsessive thoughts	1	0
Parasomnias		
Abnormal dreams	1	0
Somnambulism	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	1	0
Loss of libido	1	0
Somatic symptom disorders		
Psychogenic tremor	1	0
Suicidal and self-injurious behaviour		
Suicidal ideation	1	0
Thinking disturbances		
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	60	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Micturition urgency	1	0
Urinary incontinence	2	0
Renal failure and impairment		
Acute kidney injury	1	0
Urinary abnormalities		
Chromaturia	1	0
Urinary tract signs and symptoms NEC		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast signs and symptoms		
Breast pain	1	0
Breast swelling	1	0
Menopausal effects NEC		
Menopausal symptoms	1	0
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	12	0
Intermenstrual bleeding	2	0
Menstrual disorder	5	0
Menstruation irregular	8	0
Menstruation with decreased bleeding		
Amenorrhoea	2	0
Hypomenorrhoea	1	0
Menstruation delayed	12	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	20	0
Polymenorrhoea	2	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	1	0
Reproductive tract signs and symptoms NEC		
Genital rash	1	0
Pelvic pain	2	0
Reproductive & breast disorders SOC TOTAL	72	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	31	0
Hyperventilation	2	0
Respiration abnormal	1	0
Bronchospasm and obstruction		
Chronic obstructive pulmonary disease	1	1
Wheezing	1	0
Coughing and associated symptoms		
Cough	10	0
Haemoptysis	1	0
Productive cough	1	0
Lower respiratory tract signs and symptoms		
Pulmonary pain	1	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Nasal disorders NEC		
Epistaxis	5	0
Nasal pruritus	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	1	0
Pharyngeal ulceration	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	4	0
Upper respiratory tract signs and symptoms		
Catarrh	1	0
Oropharyngeal pain	17	0
Rhinorrhoea	6	0
Sinus pain	2	0
Sneezing	1	0
Throat irritation	1	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	91	1

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	1	0
Alopecias		
, Alopecia	1	0
Apocrine and eccrine gland disorders		
Cold sweat	5	0
Hyperhidrosis	28	-
Miliaria	1	0
Night sweats	8	
Bullous conditions		
Blister	4	0
Dermal and epidermal conditions NEC	7	
Dry skin	4	0
Pain of skin	3	
	2	1
Papule Skip burning concetion	4	0
Skin burning sensation		-
Skin warm	I	0
Dermatitis and eczema		_
Dermatitis allergic	1	0
Dermatitis atopic	1	0
Eczema	4	0
Perioral dermatitis	1	0
Skin irritation	1	0
Erythemas		
Erythema	17	0
Exfoliative conditions		
Skin exfoliation	2	0
Pruritus NEC		
Pruritus	24	0
Psoriatic conditions		
Psoriasis	2	0
Purpura and related conditions		
Petechiae	4	0
Rashes, eruptions and exanthems NEC		
Rash	30	0
Rash erythematous	11	0
Rash macular	1	0
Rash papular	2	0
Rash pruritic	7	0
Rash vesicular	4	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin vasomotor conditions		_
Livedo reticularis	1	0
Urticarias		
Urticaria	7	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	182	Ö

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Immunisations		
COVID-19 immunisation	1	0
Joint therapeutic procedures		
Joint injection	1	0
Surgical & medical procedures SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Shock	1	0
Haemorrhages NEC		
Haematoma	2	0
Haemorrhage	3	0
Non-site specific embolism and thrombosis		
Embolism	1	0
Thrombosis	3	0
Non-site specific necrosis and vascular insufficiency NEC		
Vascular compression	1	0
Non-site specific vascular disorders NEC		
Vascular pain	1	0
Vein discolouration	2	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	9	0
Pelvic venous thrombosis	1	0
Peripheral vascular disorders NEC		
Flushing	1	0
Hot flush	12	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	3	0
Raynaud's phenomenon	1	0
Varicose veins NEC		
Spider vein	1	0
Varicose vein	1	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular hypotensive disorders		
Hypotension	1	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	46	0
TOTAL REACTIONS FOR DRUG	2465	4
TOTAL REPORTS	709	
TOTAL FATAL OUTCOME REPORTS		4