

## Case Series Drug Analysis Print

**Name: All Isle of Man Spontaneous Cases Associated with COVID-19 AstraZeneca Vaccine**

Report Run Date: 07-May-2021  
Data Lock Date: 06-May-2021 18:30:03  
Earliest Reaction Date: 21-Mar-2020  
MedDRA Version: MedDRA 24.0

All Isle of Man Spontaneous Cases Associated with COVID-19 AstraZeneca Vaccine: All Isle of Man Spontaneous Cases Associated with COVID-19 AstraZeneca Vaccine

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	11	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	8	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	4	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	4	0
Vertigo	5	0
<b>Ear disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
<i>Ocular disorders NEC</i>		
Eye pain	10	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	2	0
Photophobia	3	0
<i>Visual disorders NEC</i>		
Dysmetropsia	1	0
Photopsia	2	0
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	25	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Faeces hard	1	0
<i>Flatulence, bloating and distension</i>		
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	10	0
Abdominal pain lower	1	0
Abdominal pain upper	7	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Dysphagia	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	83	0
Retching	1	0
Vomiting	27	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Lip dry	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	4	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Swollen tongue	3	0
Tongue coated	1	0
Tongue discolouration	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>190</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	13	0
Fatigue	115	0
Malaise	24	0
<i><b>Complications associated with device NEC</b></i>		
Medical device site joint pain	1	0
<i><b>Febrile disorders</b></i>		
Pyrexia	111	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	100	0
Feeling abnormal	6	0
Feeling cold	14	0
Feeling hot	4	0
Feeling of body temperature change	4	0
Hangover	2	0
Hunger	1	0
Temperature intolerance	1	0
Thirst	5	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	1	0
Loss of control of legs	1	0
<i><b>General signs and symptoms NEC</b></i>		
Illness	6	0
Influenza like illness	34	0
Local reaction	1	0
Peripheral swelling	17	0
Swelling	5	0
Swelling face	1	0
<i><b>Inflammations</b></i>		
Inflammation	4	0
<i><b>Injection site reactions</b></i>		
Injection site erythema	2	0
Injection site mass	2	0
Injection site pain	13	0
Injection site rash	1	0
Injection site scab	1	0
<i><b>Mass conditions NEC</b></i>		
Mass	1	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	1	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	1	0
Chest discomfort	1	0
Chest pain	15	0
Discomfort	3	0
Pain	31	0
Tenderness	2	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	1	0
Adverse reaction	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site erythema	2	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site hypoaesthesia	1	0
Vaccination site mass	1	0
Vaccination site movement impairment	2	0
Vaccination site pain	1	0
Vaccination site swelling	1	0
Vaccination site warmth	2	0
<b>General disorders SOC TOTAL</b>	<b>557</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Sensitisation	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Coronavirus infections</b></i>		
COVID-19	1	0
Suspected COVID-19	1	0
<i><b>Herpes viral infections</b></i>		
Herpes zoster	3	0
Oral herpes	1	0
<i><b>Infections NEC</b></i>		
Infection	5	0
Vaccination site infection	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	33	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Pneumonia	2	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	8	0
<i><b>Viral infections NEC</b></i>		
Sweating fever	4	0
<b>Infections SOC TOTAL</b>	<b>59</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	4	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle rupture	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	4	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	1	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
<b>Injuries SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate	2	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	3	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	7	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
<i>White blood cell analyses</i>		
White blood cell count	1	0
<b>Investigations SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	10	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	4	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	52	0
Joint stiffness	2	0
Joint swelling	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	58	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	4	0
Muscle spasms	8	0
Muscle tightness	1	0
Muscle twitching	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	4	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	1	0
Musculoskeletal stiffness	7	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	8	0
Limb discomfort	8	0
Musculoskeletal chest pain	1	0
Neck pain	10	0
Pain in extremity	54	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>226</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	3	1
<i>Coordination and balance disturbances</i>		
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	9	0
Loss of consciousness	1	0
Somnolence	3	0
Syncope	6	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	199	0
Sinus headache	1	0
Tension headache	5	0
Thunderclap headache	1	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	18	0
Migraine without aura	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	50	0
Dizziness postural	3	0
Head discomfort	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hypoaesthesia	13	0
Paraesthesia	16	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	4	0
Neuralgia	1	0
Taste disorder	5	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	3	0
<i>Tremor (excl congenital)</i>		
Tremor	28	0
<b>Nervous system disorders SOC TOTAL</b>	<b>382</b>	<b>1</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device malfunction events NEC</i>		
Thrombosis in device	2	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Agitation	1	0
Anxiety	2	0
Stress	1	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Mental fatigue	1	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	3	0
Disorientation	1	0
<i><b>Deliria</b></i>		
Delirium	2	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	5	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	4	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Irritability	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination, visual	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Tearfulness	1	0
<i><b>Mood disorders NEC</b></i>		
Listless	1	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	2	0
Nightmare	3	0
<i><b>Somatic symptom disorders</b></i>		
Habit cough	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>31</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Organic erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3	0
Polymenorrhoea	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	16	0
Hypopnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Bronchospasm	1	0
Wheezing	2	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	8	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	7	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Tonsillar hypertrophy	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Catarrh	1	0
Dry throat	1	0
Oropharyngeal pain	6	0
Rhinorrhoea	1	0
Sinus pain	1	0
Throat irritation	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	24	0
Night sweats	4	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	2	0
Skin burning sensation	1	0
Skin odour abnormal	1	0
Skin reaction	1	0
Skin warm	3	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	3	0
Eczema	1	0
<i>Erythemas</i>		
Erythema	9	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Pruritus NEC</i>		
Pruritus	20	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	19	0
Rash erythematous	2	0
Rash macular	3	0
Rash pruritic	2	0
<i>Urticarias</i>		
Urticaria	5	0
<b>Skin disorders SOC TOTAL</b>	<b>105</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Immunisations</i>		
Immunisation	2	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>2</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	2	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	3	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Hot flush	9	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	4	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>24</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1764</b>	<b>1</b>
<b>TOTAL REPORTS</b>	<b>480</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>1</b>