

## Case Series Drug Analysis Print

**Name: FOI 24/170 - AstraZeneca COVID-19 vaccine, batch PV46673, administered in April 2021**

Report Run Date: 18-Mar-2024  
Data Lock Date: 14-Mar-2024 18:30:03  
Earliest Reaction Date: 15-Jan-2021  
MedDRA Version: MedDRA 26.1

FOI 24/170 - All UK spontaneous suspected Adverse Drug Reaction  
AstraZeneca COVID- (ADR) reports for the AstraZeneca COVID-19 vaccine  
19 vaccine, batch administered in April 2021, batch PV46673, up to and  
PV46673, administered including 14/03/2024  
in April 2021:

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemias NEC</b></i>		
Anaemia	2	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	3	0
Lymphadenitis	1	0
Lymphadenopathy	31	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Pancytopenia	1	0
<i><b>Neutropenias</b></i>		
Neutropenia	2	0
<i><b>Thrombocytopenias</b></i>		
Heparin-induced thrombocytopenia	1	0
Thrombocytopenia	13	0
Thrombosis with thrombocytopenia syndrome	2	0
<b>Blood disorders SOC TOTAL</b>	<b>57</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	42	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	2	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	1	0
Angina pectoris	6	0
Myocardial infarction	7	0
Myocardial ischaemia	1	0
<i><b>Myocardial disorders NEC</b></i>		
Left ventricular dysfunction	1	0
Myocardial fibrosis	1	0
Myocardial oedema	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	3	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	3	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	1	0
Bradycardia	2	0
Cardiac flutter	1	0
Tachycardia	13	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	6	0
Atrial flutter	1	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>97</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	16	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	7	0
Deafness neurosensory	2	0
Deafness unilateral	1	0
Hypoacusis	1	0
Sudden hearing loss	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	42	0
Vertigo	21	0
Vertigo positional	2	0
<b>Ear disorders SOC TOTAL</b>	<b>99</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	2	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	2	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	4	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	2	0
Iritis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	4	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid rash	2	0
Swelling of eyelid	5	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haemorrhage	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	22	0
Eye swelling	2	0
Eye symptom	1	0
Eyelid pain	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye pruritus	2	0
Ocular hyperaemia	1	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	6	0
Hypoaesthesia eye	1	0
Photophobia	8	0
<i><b>Orbital structural change, deposit and degeneration</b></i>		
Lid sulcus deepened	2	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Retinal detachment	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	3	0
Metamorphopsia	1	0
Photopsia	4	0
Vision blurred	27	0
Visual brightness	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness unilateral	1	0
Visual impairment	10	0
<b>Eye disorders SOC TOTAL</b>	<b>118</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis acute	1	0
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Benign oral cavity neoplasms</i>		
Tongue cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	2	0
Toothache	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	53	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	12	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	7	0
Flatulence	2	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	37	0
Abdominal pain lower	1	0
Abdominal pain upper	32	0
Abdominal rigidity	1	0
Gastrointestinal pain	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	5	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	16	0
Anal incontinence	2	0
Odynophagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Mesenteric artery thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	1	0
Gingival pain	3	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gingival swelling	2	0
Noninfective gingivitis	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	1	0
<b><i>Intestinal haemorrhages</i></b>		
Rectal haemorrhage	1	0
Small intestinal haemorrhage	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	227	0
Retching	2	0
Vomiting	73	0
Vomiting projectile	1	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematochezia	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	5	0
Lip dry	1	0
Salivary hypersecretion	2	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Oral lichen planus	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	3	0
Oral pain	3	0
Paraesthesia oral	6	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	4	0
Mouth swelling	1	0
Palatal swelling	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	8	0
Stomatitis	2	0
<b><i>Tongue disorders</i></b>		
Tongue haemorrhage	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	2	0
Swollen tongue	2	0
Tongue discomfort	1	0
<b><i>Tooth missing</i></b>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>553</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site urticaria	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	35	0
Chronic fatigue syndrome	1	0
Fatigue	356	0
Malaise	88	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Febrile disorders</i>		
Pyrexia	343	0
<i>Feelings and sensations NEC</i>		
Chills	259	0
Feeling abnormal	21	0
Feeling cold	35	0
Feeling hot	18	0
Feeling jittery	1	0
Feeling of body temperature change	5	0
Hunger	1	0
Thirst	8	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crying	5	0
Illness	19	0
Influenza like illness	54	0
Peripheral swelling	51	0
Swelling	34	0
Swelling face	2	0
<i>Inflamations</i>		
Granuloma	1	0
Inflammation	5	0
<i>Infusion site reactions</i>		
Infusion site pain	1	0
<i>Injection site reactions</i>		
Injection site atrophy	1	0
Injection site bruising	1	0
Injection site erythema	3	0
Injection site mass	8	0
Injection site pain	34	0
Injection site reaction	1	0
Injection site swelling	2	0
Injection site warmth	3	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Oedema NEC</i>		
Oedema	2	0
Oedema peripheral	2	0

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<b>General disorders</b> General disorders cont'd		
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	8	0
Chest discomfort	17	0
Chest pain	45	0
Discomfort	8	0
Facial pain	1	0
Inflammatory pain	1	0
Non-cardiac chest pain	2	0
Pain	145	0
Tenderness	8	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	2	0
Drug ineffective	4	0
Therapeutic response unexpected	1	0
Vaccination failure	2	0
<i><b>Vaccination site reactions</b></i>		
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	7	0
Vaccination site induration	1	0
Vaccination site mass	4	0
Vaccination site movement impairment	2	0
Vaccination site pain	12	0
Vaccination site pruritus	2	0
Vaccination site swelling	1	0
Vaccination site warmth	1	0
<i><b>Withdrawal and rebound effects</b></i>		
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>1687</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatic vascular disorders</i>		
Hepatic vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	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>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	10	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Reaction to preservatives	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immunosuppression	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Diverticulitis	1	0
Gastroenteritis	2	0
<i><b>Bacterial infections NEC</b></i>		
Bacterial infection	1	0
Cellulitis	3	0
<i><b>Campylobacter infections</b></i>		
Campylobacter colitis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Myelitis	1	0
<i><b>Coronavirus infections</b></i>		
COVID-19	21	0
COVID-19 pneumonia	1	0
Post-acute COVID-19 syndrome	1	0
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	2	0
<i><b>Ear infections</b></i>		
Labyrinthitis	2	0
<i><b>Eye and eyelid infections</b></i>		
Hordeolum	1	0
<i><b>Herpes viral infections</b></i>		
Herpes ophthalmic	1	0
Herpes zoster	16	0
Nasal herpes	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	6	0
Varicella	2	0
<i><b>Infections NEC</b></i>		
Infection	2	0
<i><b>Influenza viral infections</b></i>		
Influenza	41	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	5	0
Pneumonia	2	0
<i><b>Rubeola viral infections</b></i>		
Measles	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	2	0
<i><b>Staphylococcal infections</b></i>		
Furuncle	1	0
<i><b>Tinea infections</b></i>		
Body tinea	1	0
<i><b>Upper respiratory tract infections</b></i>		
Laryngitis	1	0
Nasopharyngitis	18	0
Sinusitis	4	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Gastroenteritis viral	1	0
Meningitis viral	1	0
Sweating fever	6	0

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<b>Infections</b>		
Infections cont'd		
Viral labyrinthitis	1	0
Viral pericarditis	1	0
Viral pharyngitis	1	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>155</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Abdominal and gastrointestinal injuries NEC</b></i>		
Oral contusion	1	0
<i><b>Cardiac and vascular procedural complications</b></i>		
Deep vein thrombosis postoperative	1	0
<i><b>Cerebral injuries NEC</b></i>		
Subdural haematoma	1	1
<i><b>Conditions caused by cold</b></i>		
Chillblains	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	6	0
Maternal exposure during pregnancy	5	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	2	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Epicondylitis	2	0
Muscle injury	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Arthropod sting	1	0
Electric shock	1	0
Fall	2	0
Wound haemorrhage	1	0
<i><b>Non-site specific procedural complications</b></i>		
Infusion related reaction	1	0
Injection related reaction	2	0
<i><b>Off label uses</b></i>		
Off label use	3	0
<i><b>Product administration errors and issues</b></i>		
Incorrect dose administered	1	0
<i><b>Radiation injuries</b></i>		
Sunburn	1	0
<i><b>Renal and urinary tract injuries NEC</b></i>		
Kidney rupture	1	0
<i><b>Site specific injuries NEC</b></i>		
Limb injury	4	0
<i><b>Skin injuries NEC</b></i>		
Contusion	25	0
Skin injury	1	0
<i><b>Vaccination related complications</b></i>		
Immunisation reaction	2	0
<b>Injuries SOC TOTAL</b>	<b>70</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood counts NEC</b></i>		
Full blood count	1	0
<i><b>Bone marrow and immune tissue histopathology procedures</b></i>		
Biopsy lymph gland	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>Cell marker analyses</b></i>		
Prostatic specific antigen increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
Blood fibrinogen decreased	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	2	0
International normalised ratio abnormal	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram abnormal	2	0
<i><b>Endocrine analyses and imaging NEC</b></i>		
Hormone level abnormal	2	0
<i><b>Faecal analyses NEC</b></i>		
Faecal calprotectin increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	10	0
Heart rate abnormal	1	0
Heart rate increased	24	0
Heart rate irregular	2	0
Pulse pressure increased	1	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Alanine aminotransferase increased	2	0
Liver function test	1	0
<i><b>Investigations NEC</b></i>		
Blood test	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	4	0
Body temperature decreased	1	0
Body temperature fluctuation	2	0
Body temperature increased	5	0
General physical condition abnormal	1	0
Skin temperature	1	0
Weight decreased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	2	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Total lung capacity decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine	2	0
Blood urine present	2	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure abnormal	1	0
Blood pressure decreased	1	0
Blood pressure increased	1	0
Blood pressure measurement	1	0



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Investigations</b>		
Investigations cont'd		
<i><b>Virus identification and serology</b></i>		
Coronavirus test	3	0
<i><b>White blood cell analyses</b></i>		
CD4 lymphocytes decreased	1	0
Eosinophil count increased	2	0
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>90</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	44	0
Food refusal	2	0
Hypophagia	1	0
Increased appetite	1	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal weight gain	1	0
Feeding disorder	2	0
Poor feeding infant	1	0
Weight loss poor	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Glucose tolerance impaired	1	0
Hyperglycaemia	1	0
<i><b>Hyperlipidaemias NEC</b></i>		
Hyperlipidaemia	1	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	1	0
<i><b>Metabolic disorders NEC</b></i>		
Hypometabolism	1	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	6	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Folate deficiency	1	0
Vitamin B12 deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>70</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	7	0
Arthropathy	1	0
Haemarthrosis	1	0
Sympathetic posterior cervical syndrome	1	0
<b><i>Bone disorders NEC</i></b>		
Bone disorder	1	0
Osteitis	1	0
Osteonecrosis of jaw	1	0
Spinal disorder	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	10	0
Pain in jaw	4	0
Spinal pain	2	0
<b><i>Bursal disorders</i></b>		
Bursitis	3	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	2	0
Scleroderma	1	0
<b><i>Joint related disorders NEC</i></b>		
Joint lock	1	0
Periarthritis	6	0
Temporomandibular joint syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	164	0
Joint effusion	1	0
Joint stiffness	2	0
Joint swelling	12	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	2	0
Myalgia	161	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle fatigue	8	0
Muscle spasms	29	0
Muscle swelling	1	0
Muscle twitching	3	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	16	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Mobility decreased	2	0
Musculoskeletal stiffness	25	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	26	0
Limb discomfort	20	0
Musculoskeletal chest pain	4	0
Musculoskeletal pain	2	0
Neck pain	21	0
Pain in extremity	171	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	1	0
<b><i>Rheumatoid arthropathies</i></b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Rheumatoid arthritis	2	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	1	0
Groin pain	2	0
<b>Spondyloarthropathies</b>		
Arthritis reactive	2	0
<b>Synovial disorders</b>		
Synovitis	1	0
<b>Tendon disorders</b>		
Enthesopathy	1	0
Tendonitis	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>727</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Squamous cell carcinoma	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Meningioma	1	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Respiratory tract small cell carcinomas</i>		
Small cell lung cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery aneurysm	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	5	0
Haemorrhagic stroke	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
<i>Coordination and balance disturbances</i>		
Balance disorder	7	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Alexia	1	0
Apraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	31	0
Loss of consciousness	8	0
Somnolence	20	0
Stupor	1	0
Syncope	19	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Dyskinesia	2	0
Hyperkinesia	1	0
Hypokinesia	3	0
Motor dysfunction	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	1	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	5	0
Cold-stimulus headache	1	0
Exertional headache	1	0
Headache	535	0
Occipital neuralgia	2	0
Primary stabbing headache	1	0
Sinus headache	4	0
Tension headache	12	0
Vascular headache	1	0
<i>Increased intracranial pressure disorders</i>		
Brain compression	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Lumbar spinal cord and nerve root disorders</i></b>		
Sciatica	1	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	8	0
Memory impairment	4	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	1	0
Disturbance in attention	3	0
<b><i>Migraine headaches</i></b>		
Migraine	49	0
Migraine with aura	2	0
Typical aura without headache	1	0
Vestibular migraine	2	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	1	0
<b><i>Nervous system cysts and polyps</i></b>		
Arachnoid cyst	1	0
<b><i>Nervous system disorders NEC</i></b>		
Nervous system disorder	1	0
<b><i>Neurologic visual problems NEC</i></b>		
Tunnel vision	2	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Brain fog	8	0
Dizziness	167	0
Dizziness postural	11	0
Head discomfort	12	0
Neurological symptom	2	0
Presyncope	6	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	1	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	2	0
Parosmia	3	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	2	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	6	0
Hyperaesthesia	2	0
Hypoaesthesia	49	0
Paraesthesia	72	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiparesis	2	0
Hemiplegia	1	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	2	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	1	0
Parkinson's disease	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	4	0
<b><i>Seizures and seizure disorders NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Epilepsy	3	0
Seizure	13	0
Status epilepticus	1	0
Tonic convulsion	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	4	0
Aura	1	0
Dysgeusia	16	0
Electric shock sensation	2	0
Neuralgia	11	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
Sensory loss	4	0
Taste disorder	3	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	3	0
Incoherent	2	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	6	0
<b>Tremor (excl congenital)</b>		
Essential tremor	2	0
Tremor	59	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	2	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1255</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Anxiety	19	0
Nervousness	7	0
Stress	1	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Aggression	1	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Mental fatigue	5	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	20	0
Disorientation	2	0
<i><b>Deliria</b></i>		
Delirium	4	0
<i><b>Depressive disorders</b></i>		
Depression	10	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	25	0
Middle insomnia	1	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	7	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	2	0
Euphoric mood	1	0
Irritability	1	0
Mood altered	1	0
<i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i>		
Fear	1	0
Fear of death	1	0
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	6	0
Hallucination, auditory	2	0
Hallucination, visual	2	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	3	0
<i><b>Mental disorders NEC</b></i>		
Mental disorder	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	8	0
Tearfulness	1	0
<i><b>Mood disorders NEC</b></i>		
Apathy	1	0
Laziness	1	0
Listless	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic attack	2	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	3	0
Nightmare	4	0
Sleep terror	2	0
<i><b>Psychotic disorder NEC</b></i>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Psychotic disorder	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	5	0
<b>Stress disorders</b>		
Post-traumatic stress disorder	1	0
<b>Thinking disturbances</b>		
Bradyphrenia	2	0
Thinking abnormal	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>158</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	2	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Nephrotic syndrome	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	1	0
Renal failure	1	0
Renal impairment	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	1	0
Proteinuria	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Renal pain	6	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	7	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	2	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	15	0
Intermenstrual bleeding	4	0
Menstrual disorder	18	0
Menstruation irregular	20	0
Ovulation pain	3	0
Premenstrual pain	1	0
Premenstrual syndrome	1	0
Withdrawal bleed	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	4	0
Hypomenorrhoea	3	0
Menstruation delayed	31	0
Oligomenorrhoea	3	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	51	0
Polymenorrhoea	10	0
<i><b>Penile disorders NEC (excl erection and ejaculation)</b></i>		
Penile blister	1	0
Penile size reduced	1	0
Penis disorder	1	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	1	0
<i><b>Sexual function and fertility disorders NEC</b></i>		
Dyspareunia	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular disorder	1	0
Testicular oedema	1	0
Testicular pain	2	0
<i><b>Uterine disorders NEC</b></i>		
Endometriosis	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	20	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vaginal discharge	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>206</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	64	0
Hypopnoea	1	0
Respiration abnormal	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	8	0
Wheezing	3	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	23	0
Haemoptysis	4	0
Productive cough	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
Pleuritic pain	1	0
Pulmonary pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	31	0
Nasal dryness	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	2	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	3	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	8	1
Pulmonary thrombosis	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Respiratory symptom	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Catarrh	3	0
Choking	1	0
Dry throat	3	0
Oropharyngeal blistering	1	0
Oropharyngeal pain	25	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	10	0
Sinus pain	5	0
Sneezing	1	0
Throat tightness	4	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>220</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	4	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	16	0
Hyperhidrosis	57	0
Miliaria	1	0
Night sweats	15	0
<i>Bullous conditions</i>		
Blister	3	0
Blister rupture	1	0
Blood blister	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Pain of skin	8	0
Sensitive skin	8	0
Skin burning sensation	4	0
Skin discolouration	2	0
Skin induration	1	0
Skin lesion	1	0
Skin reaction	2	0
Skin sensitisation	1	0
Skin warm	4	0
Skin weeping	1	0
Sticky skin	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	2	0
Eczema	1	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	22	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Parapsoriasis	1	0
<i>Pruritus NEC</i>		
Pruritus	76	0
<i>Psoriatic conditions</i>		
Psoriasis	2	0
<i>Purpura and related conditions</i>		
Petechiae	6	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	86	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash erythematous	16	0
Rash macular	6	0
Rash maculo-papular	1	0
Rash morbilliform	3	0
Rash papular	4	0
Rash pruritic	28	0
Rash vesicular	1	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin erosion	1	0
Skin ulcer	1	0
<b><i>Urticarias</i></b>		
Cold urticaria	1	0
Urticaria	30	0
Urticaria chronic	1	0
<b>Skin disorders SOC TOTAL</b>	<b>438</b>	<b>0</b>



## Case Series Drug Analysis Print

**Name: FOI 24/170 - AstraZeneca COVID-19 vaccine, batch PV46673, administered in April 2021**

Report Run Date: 18-Mar-2024  
Earliest Reaction Date: 15-Jan-2021

Data Lock Date: 14-Mar-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
Tooth restoration	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Immunisations</i>		
COVID-19 immunisation	1	0
Immunisation	1	0
<i>Limb therapeutic procedures</i>		
Limb operation	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	4	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>10</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/170 - AstraZeneca COVID-19 vaccine, batch PV46673, administered in April 2021**

Report Run Date: 18-Mar-2024  
Earliest Reaction Date: 15-Jan-2021

Data Lock Date: 14-Mar-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Accelerated and malignant hypertension</i>		
Malignant hypertension	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	18	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Thrombosis	21	0
Venous thrombosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vasodilatation	1	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	10	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	2	0
Hot flush	14	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	14	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	4	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Varicose veins NEC</i>		
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	3	0
<b>Vascular disorders SOC TOTAL</b>	<b>121</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>6192</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>1669</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>