

Case Series Drug Analysis Print

**Name: Batch Number AB0013/ ABOO13 / ABO013 / AB0O13
Astrazeneca COVID-19 Vaccine VAP FOI 2024/00103**

Report Run Date: 04-Jun-2024
Data Lock Date: 16-May-2024 18:30:03
Earliest Reaction Date: 12-Feb-2020
MedDRA Version: MedDRA 27.0

Batch Number AB0013/ ABOO13 / ABO013 / AB0O13
Astrazeneca COVID-19 Vaccine VAP FOI 2024/00103:
All UK spontaneous suspected Adverse Drug Reaction (ADR) reports up to and including 16/05/2024 for suspect drug Astra Zeneca COVID-19 Vaccine with Batch Number AB0013/ ABOO13/ ABO013 / AB0O13

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	10	0
Lymphadenopathy	65	0
Lymphatic disorder	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Spleen disorders</i>		
Splenic infarction	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	9	0
Thrombocytopenic purpura	1	0
Thrombosis with thrombocytopenia syndrome	1	0
Blood disorders SOC TOTAL	98	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	83	0
<i>Cardiomyopathies</i>		
Dilated cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	2	1
Angina pectoris	3	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Myocardial infarction	7	1
Myocardial ischaemia	1	0
Prinzmetal angina	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Cardiac flutter	4	0
Tachycardia	27	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	6	0
Atrial flutter	1	0
Sinus tachycardia	2	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Cardio-respiratory arrest	1	1
Cardiac disorders SOC TOTAL	154	3

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear disorder	1	0
Ear haemorrhage	1	0
Ear pain	28	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness neurosensory	1	0
Hypoacusis	4	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	5	0
Tinnitus	52	0
Vertigo	26	0
Vertigo positional	4	0
Ear disorders SOC TOTAL	131	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
Haemorrhagic adrenal infarction	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Secondary adrenocortical insufficiency	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
Thyrotoxic crisis	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	1	0
<i>Lacrimation disorders</i>		
Dry eye	4	0
Lacrimation increased	4	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	3	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye oedema	1	0
Eye pain	57	0
Eye swelling	9	0
Eyelid disorder	1	0
Ocular discomfort	2	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye discharge	2	0
Eye irritation	3	0
Eye pruritus	3	0
Ocular hyperaemia	5	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Eyelid sensory disorder	1	0
Photophobia	21	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal artery occlusion	1	0
Retinal vascular occlusion	1	0
<i>Retinopathies NEC</i>		
Retinopathy	1	0
<i>Visual colour distortions</i>		
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	5	0
Photopsia	4	0
Vision blurred	34	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Night blindness	1	0
Visual impairment	6	0
Eye disorders SOC TOTAL	183	0

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Gastrointestinal disorders		
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Dental disorders NEC</i>		
Teething	2	0
<i>Dental pain and sensation disorders</i>		
Toothache	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	135	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	9	0
Eructation	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	9	0
Flatulence	9	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	70	0
Abdominal pain lower	2	0
Abdominal pain upper	69	0
Gastrointestinal pain	3	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	6	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	21	0
Dysphagia	2	0
Odynophagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	1	0
Gingival pain	3	0
Gingival swelling	1	0
Gingival ulceration	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Faecal vomiting	1	0
Nausea	564	0
Retching	12	0
Vomiting	193	0
Vomiting projectile	4	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	3	0
Haematochezia	2	0
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	1	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	16	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Oral lichen planus	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	2	0
<i>Oral soft tissue signs and symptoms</i>		
Burning mouth syndrome	1	0
Hypoaesthesia oral	7	0
Lip pain	1	0
Lip pruritus	1	0
Oral mucosal blistering	1	0
Oral pain	3	0
Paraesthesia oral	13	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	13	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Lip ulceration	1	0
Mouth ulceration	6	0
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	7	0
Swollen tongue	8	0
Tongue blistering	1	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue rough	1	0
Gastrointestinal disorders SOC TOTAL	1241	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Administration site swelling	1	0
Puncture site reaction	1	0
<i>Application site reactions</i>		
Application site bruise	1	0
Application site erythema	1	0
Application site pain	1	0
<i>Asthenic conditions</i>		
Asthenia	83	0
Chronic fatigue syndrome	6	0
Fatigue	812	0
Malaise	212	0
<i>Body temperature altered</i>		
Hypothermia	3	0
<i>Death and sudden death</i>		
Death	1	1
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	944	0
<i>Feelings and sensations NEC</i>		
Chills	827	0
Feeling abnormal	53	0
Feeling cold	111	0
Feeling drunk	3	0
Feeling hot	36	0
Feeling of body temperature change	20	0
Hangover	3	0
Hunger	2	0
Temperature intolerance	1	0
Thirst	24	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	4	0
Loss of control of legs	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	5	0
Crying	3	0
Exercise tolerance decreased	2	0
Illness	90	0
Induration	1	0
Influenza like illness	166	0
Local reaction	1	0
Peripheral swelling	85	0
Swelling	34	0
Swelling face	26	0
<i>Implant and catheter site reactions</i>		
Implant site discharge	1	0
Implant site warmth	1	0
<i>Inflammations</i>		
Inflammation	12	0
<i>Injection site reactions</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injected limb mobility decreased	1	0
Injection site bruising	2	0
Injection site discomfort	1	0
Injection site erythema	13	0
Injection site haemorrhage	1	0
Injection site inflammation	2	0
Injection site joint erythema	1	0
Injection site mass	27	0
Injection site movement impairment	1	0
Injection site pain	78	0
Injection site pruritus	4	0
Injection site rash	4	0
Injection site scar	1	0
Injection site swelling	5	0
Injection site warmth	6	0
Interactions		
Drug interaction	1	0
Mass conditions NEC		
Mass	1	0
Mucosal findings abnormal		
Mucosal haemorrhage	1	0
Oedema NEC		
Oedema peripheral	2	0
Pain and discomfort NEC		
Axillary pain	4	0
Chest discomfort	38	0
Chest pain	73	0
Discomfort	2	0
Facial discomfort	1	0
Facial pain	4	0
Hernia pain	1	0
Non-cardiac chest pain	1	0
Pain	236	0
Tenderness	35	0
Therapeutic and nontherapeutic responses		
Adverse reaction	1	0
Drug ineffective	2	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	11	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	2	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	13	0
Vaccination site pain	40	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pruritus	1	0
Vaccination site rash	2	0
Vaccination site swelling	10	0
Vaccination site warmth	7	0
General disorders SOC TOTAL	4237	2

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic vascular disorders</i>		
Hepatic vein thrombosis	1	0
Portal vein thrombosis	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Drug-induced liver injury	1	0
Hepatic disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	21	0
Serum sickness	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Drug hypersensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	14	0
Anaphylactoid shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	43	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	6	0
Injection site cellulitis	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Mastitis	2	0
<i>Central nervous system and spinal infections</i>		
Meningitis	1	0
Myelitis	2	0
<i>Coronavirus infections</i>		
COVID-19	16	0
<i>Coxiella infections</i>		
Q fever	4	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Herpes viral infections</i>		
Genital herpes	1	0
Herpes zoster	13	0
Oral herpes	4	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	10	0
Injection site abscess	1	0
Localised infection	1	0
<i>Influenza viral infections</i>		
Influenza	117	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	4	0
Pneumonia	4	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Septic shock	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Skin infection	3	0
<i>Tinea infections</i>		
Body tinea	1	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	27	0
Pharyngitis	1	0
Sinusitis	5	0
<i>Urinary tract infections</i>		

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Infections		
Infections cont'd		
Cystitis	1	0
Renal abscess	1	0
Urinary tract infection	5	0
<i>Viral infections NEC</i>		
Eye infection viral	1	0
Hepatitis viral	1	0
Meningitis viral	1	0
Sweating fever	15	0
Viral diarrhoea	1	0
Viral rash	1	0
Infections SOC TOTAL	263	0

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Injuries		
<i>Atmospheric pressure injuries</i>		
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Subarachnoid haematoma	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Traumatic haemothorax	1	0
<i>Conditions caused by cold</i>		
Chillblains	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	8	0
Maternal exposure during pregnancy	4	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
Exposure to toxic agent	1	0
<i>Eye injuries NEC</i>		
Eye contusion	4	0
<i>Limb fractures and dislocations</i>		
Ankle fracture	1	0
Foot fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	1	0
Medication error	1	0
Product use issue	1	0
Vaccination error	2	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	2	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	3	0
<i>Non-site specific injuries NEC</i>		
Arthropod sting	1	0
Electric shock	1	0
Fall	6	0
Injury	1	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Injection related reaction	16	0
Post procedural complication	2	0
<i>Off label uses</i>		
Off label use	2	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	2	0
Incorrect product administration duration	1	0

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Injuries Injuries cont'd		
<i>Reproductive tract and breast procedural complications</i>		
Postmastectomy lymphoedema syndrome	1	0
<i>Site specific injuries NEC</i>		
Limb injury	5	0
Nasal injury	1	0
<i>Skin injuries NEC</i>		
Contusion	37	0
<i>Vaccination related complications</i>		
Immunisation reaction	1	0
Injuries SOC TOTAL	120	0

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Reaction Name	Total	Fatal
Investigations		
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	1	0
<i>Blood gas and acid base analyses</i>		
Blood pH	1	0
Oxygen saturation	1	0
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	2	0
Blood glucose fluctuation	1	0
Blood glucose increased	6	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
Heart sounds	1	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	1	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	3	0
International normalised ratio abnormal	1	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood insulin decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	17	0
Heart rate abnormal	1	0
Heart rate decreased	3	0
Heart rate increased	42	0
Heart rate irregular	6	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test abnormal	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test abnormal	3	0
<i>Mineral and electrolyte analyses</i>		
Blood potassium decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	18	0
Body temperature abnormal	3	0
Body temperature decreased	3	0
Body temperature fluctuation	2	0
Body temperature increased	27	0
Grip strength	1	0
Skin temperature	1	0
Weight decreased	3	0
<i>Platelet analyses</i>		
Platelet count decreased	4	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Forced expiratory volume increased	1	0
Peak expiratory flow rate decreased	1	0
Urinalysis NEC		
Blood urine present	1	0
Urine analysis abnormal	2	0
Urinary tract function analyses NEC		
Urine output	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	7	0
Blood pressure measurement	1	0
Virus identification and serology		
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 antibody test positive	1	0
Vitamin analyses		
Blood folate decreased	1	0
Vitamin B12 decreased	1	0
White blood cell analyses		
Lymphocyte count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	185	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	143	0
Food refusal	1	0
Increased appetite	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	4	0
<i>Diabetic complications NEC</i>		
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	4	0
Food aversion	1	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0
Hyperglycaemia	4	0
Insulin resistance	1	0
Metabolic syndrome	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	7	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	175	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	12	0
Palindromic rheumatism	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	19	0
Pain in jaw	13	0
Spinal pain	7	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
<i>Joint related disorders NEC</i>		
Greater trochanteric pain syndrome	1	0
Joint lock	1	0
Periarthritis	5	0
<i>Joint related signs and symptoms</i>		
Arthralgia	416	0
Joint noise	1	0
Joint stiffness	5	0
Joint swelling	20	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle pains</i>		
Fibromyalgia	4	0
Myalgia	457	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle fatigue	18	0
Muscle spasms	46	0
Muscle swelling	1	0
Muscle tightness	1	0
Muscle twitching	5	0
<i>Muscle tone abnormalities</i>		
Torticollis	1	0
Trismus	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	41	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	25	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	106	0
Flank pain	1	0
Limb discomfort	30	0
Musculoskeletal chest pain	7	0
Musculoskeletal discomfort	4	0
Musculoskeletal pain	3	0
Neck pain	45	0
Pain in extremity	318	0
Rheumatic disorder	3	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	3	0
Muscle & tissue disorders SOC TOTAL	1634	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Metastases to specified sites</i>		
Metastases to lung	1	1
<i>Non-Hodgkin's lymphomas NEC</i>		
Cutaneous lymphoma	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i>		
NEC		
Lung neoplasm malignant	1	0
Neoplasms SOC TOTAL	4	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Carotid artery thrombosis	1	0
Cerebellar stroke	1	0
Cerebral ischaemia	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	12	0
Haemorrhagic transformation stroke	1	0
Ischaemic stroke	3	0
Middle cerebral artery stroke	1	0
Subarachnoid haemorrhage	3	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
Cerebral venous thrombosis	1	0
Transverse sinus thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	14	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
<i>Dementia (excl Alzheimer's type)</i>		
Frontotemporal dementia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	63	0
Loss of consciousness	16	0
Somnolence	34	0
Stupor	1	0
Syncope	26	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	6	0
Facial paralysis	5	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Cluster headache	15	0
Drug withdrawal headache	1	0
Headache	1362	0
Primary stabbing headache	2	0
Sinus headache	12	0
Tension headache	20	0
Vascular headache	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Memory loss (excl dementia)		
Amnesia	8	0
Memory impairment	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	10	0
Mental impairment	2	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	2	0
Migraine	110	0
Migraine with aura	1	0
Retinal migraine	1	0
Vestibular migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis relapse	1	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	2	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Brain fog	9	0
Dizziness	343	0
Dizziness exertional	3	0
Dizziness postural	42	0
Head discomfort	3	0
Neurological symptom	2	0
Persistent postural-perceptual dizziness	1	0
Presyncope	7	0
Unresponsive to stimuli	1	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	1	0
Muscle spasticity	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	6	0
Parosmia	7	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	2	0
Burning sensation	14	0
Formication	1	0
Hyperaesthesia	1	0
Hypoaesthesia	63	0
Paraesthesia	102	0
Paralysis and paresis (excl cranial nerve)		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hemiparesis	2	0
Hemiplegia	3	0
Monoparesis	1	0
Paralysis	4	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	5	0
Partial simple seizures NEC		
Simple partial seizures	1	0
Peripheral neuropathies NEC		
Neuritis	1	0
Neuropathy peripheral	4	0
Seizures and seizure disorders NEC		
Change in seizure presentation	1	0
Epilepsy	7	0
Febrile convulsion	2	0
Partial seizures	2	0
Seizure	25	0
Seizure cluster	1	0
Tonic convulsion	2	0
Sensory abnormalities NEC		
Ageusia	14	0
Complex regional pain syndrome	2	0
Dysgeusia	36	0
Neuralgia	25	0
Restless legs syndrome	2	0
Sensory disturbance	2	0
Sensory loss	1	0
Taste disorder	7	0
Sleep disturbances NEC		
Sleep deficit	2	0
Speech and language abnormalities		
Dysarthria	5	0
Incoherent	1	0
Speech disorder	2	0
Structural brain disorders NEC		
Brain injury	1	0
Transient cerebrovascular events		
Transient ischaemic attack	6	0
Tremor (excl congenital)		
Tremor	192	0
Nervous system disorders SOC TOTAL	2746	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Labour onset and length abnormalities</i>		
Premature rupture of membranes	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy conditions SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Amnestic symptoms</i>		
Paramnesia	1	0
<i>Anxiety symptoms</i>		
Anxiety	11	0
Nervousness	8	0
<i>Behaviour and socialisation disturbances</i>		
Asocial behaviour	1	0
Paranoia	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
Distractibility	1	0
Mental fatigue	11	0
<i>Confusion and disorientation</i>		
Confusional state	29	0
Disorientation	9	0
<i>Deliria</i>		
Delirium	10	0
<i>Depressive disorders</i>		
Depression	13	0
Major depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	44	0
Middle insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	8	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Emotional distress	2	0
Euphoric mood	1	0
Irritability	4	0
Mood altered	3	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	12	0
<i>Impulse control disorders</i>		
Impulse-control disorder	1	0
<i>Increased physical activity levels</i>		
Restlessness	9	0
<i>Mental disorders NEC</i>		
Mental status changes	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
Depressed mood	10	0
Negative thoughts	1	0
<i>Mood alterations with manic symptoms</i>		
Mania	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	5	0
<i>Orgasmic disorders and disturbances</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Anorgasmia	1	0
Panic attacks and disorders		
Panic attack	2	0
Panic reaction	1	0
Parasomnias		
Abnormal dreams	6	0
Nightmare	4	0
Sleep talking	1	0
Sleep terror	1	0
Psychiatric elimination disorders		
Enuresis	2	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Sexual desire disorders		
Libido decreased	1	0
Sleep disorders NEC		
Sleep disorder	8	0
Speech articulation and rhythm disturbances		
Dysphemia	2	0
Stress disorders		
Post-traumatic stress disorder	1	0
Suicidal and self-injurious behaviour		
Self-injurious ideation	1	0
Suicidal ideation	2	0
Thinking disturbances		
Bradyphrenia	1	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	243	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Dysuria	3	0
Incontinence	1	0
Micturition urgency	2	0
Pollakiuria	7	0
Urinary incontinence	6	0
<i>Renal failure and impairment</i>		
Chronic kidney disease	1	0
Renal failure	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	4	0
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	15	0
Renal & urinary disorders SOC TOTAL	43	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	4	0
Breast swelling	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	2	0
Intermenstrual bleeding	4	0
Menstrual disorder	7	0
Menstruation irregular	6	0
Withdrawal bleed	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	5	0
Hypomenorrhoea	2	0
Menstruation delayed	7	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	22	0
Polymenorrhoea	3	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	2	0
<i>Uterine disorders NEC</i>		
Uterine enlargement	1	0
Uterine haemorrhage	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	7	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	105	0
Dyspnoea at rest	1	0
Hyperventilation	1	0
Hypopnoea	5	0
Respiration abnormal	3	0
Respiratory arrest	1	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	5	0
Bronchospasm	1	0
Wheezing	6	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	2	0
<i>Coughing and associated symptoms</i>		
Cough	54	0
Haemoptysis	2	0
Productive cough	7	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	3	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	7	0
<i>Nasal disorders NEC</i>		
Epistaxis	13	0
Nasal dryness	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
Sinus polyp	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	3	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
Pneumothorax spontaneous	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	24	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	1	0
Painful respiration	1	0
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	0
Lung disorder	1	0
Pulmonary mass	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Choking	1	0
Dry throat	9	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Dysphonia	3	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	3	0
Oropharyngeal pain	56	0
Rhinalgia	1	0
Rhinorrhoea	25	0
Sinus pain	8	0
Sneezing	8	0
Throat irritation	4	0
Throat tightness	2	0
Yawning	4	0
Respiratory disorders SOC TOTAL	386	3

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	5	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	24	0
Hyperhidrosis	167	0
Miliaria	3	0
Night sweats	28	0
<i>Bullous conditions</i>		
Blister	5	0
Blood blister	1	0
Pemphigus	1	0
<i>Connective tissue disorders</i>		
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	10	0
Pain of skin	14	0
Sensitive skin	11	0
Skin burning sensation	9	0
Skin discolouration	4	0
Skin induration	1	0
Skin reaction	7	0
Skin sensitisation	2	0
Skin swelling	2	0
Skin warm	4	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	5	0
Dermatitis allergic	5	0
Eczema	7	0
Skin irritation	2	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug reaction with eosinophilia and systemic symptoms	1	0
<i>Erythemas</i>		
Erythema	44	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	5	0
<i>Pilar disorders NEC</i>		
Hair colour changes	1	0
Piloerection	2	0
Trichorrhexis	1	0
<i>Pruritus NEC</i>		
Pruritus	114	0
<i>Psoriatic conditions</i>		

Case Series Drug Analysis Print

Name: Batch Number AB0013/ ABOO13 / ABO013 / AB0O13
Astrazeneca COVID-19 Vaccine VAP FOI 2024/00103

Report Run Date: 04-Jun-2024

Data Lock Date: 16-May-2024 18:30:03

Earliest Reaction Date: 12-Feb-2020

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Guttate psoriasis	1	0
Psoriasis	2	0
Purpura and related conditions		
Petechiae	4	0
Purpura	2	0
Rashes, eruptions and exanthems NEC		
Rash	103	0
Rash erythematous	32	0
Rash macular	4	0
Rash papular	7	0
Rash pruritic	22	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin ulcer	1	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin dystrophies		
Skin wrinkling	1	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Urticarias		
Idiopathic urticaria	1	0
Urticaria	24	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	704	0

Case Series Drug Analysis Print

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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Antiinfective therapies</i>		
Antibiotic therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	2	0
Immunisation	3	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	2	0
Rest regimen	1	0
Surgical & medical procedures SOC TOTAL	9	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	1	0
Aortic thrombosis	1	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Peripheral circulatory failure	1	0
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	9	0
<i>Lymphoedemas</i>		
Lymphoedema	5	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Embolism arterial	1	0
Thrombosis	23	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	7	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	16	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	13	0
Hot flush	34	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	26	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	16	0
<i>Vascular hypotensive disorders</i>		
Hypotension	13	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	196	0
TOTAL REACTIONS FOR DRUG	12905	9

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
TOTAL REPORTS	3262	
TOTAL FATAL OUTCOME REPORTS		9