

Case Series Drug Analysis Print

**Name: FOI 21/864 Quadrivalent Influenza (inactivated) Vaccine
DAP**

Report Run Date: 17-Aug-2021
Data Lock Date: 09-Aug-2021 18:30:04
Earliest Reaction Date: 09-Oct-1963
MedDRA Version: MedDRA 24.0

FOI 21/864 All spontaneous suspected UK Adverse Drug Reaction
Quadrivalent Influenza (ADR) reports associated with quadrivalent influenza
(inactivated) Vaccine virus (inactivated) vaccine
DAP:

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	4	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	2	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Coagulopathies</i>		
Disseminated intravascular coagulation	2	0
<i>Leukocytoses NEC</i>		
Monocytosis	1	0
Neutrophilia	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	6	0
Lymphadenopathy	70	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	1
Pancytopenia	1	0
Pure white cell aplasia	2	0
<i>Neutropenias</i>		
Neutropenia	6	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	9	0
Thrombocytopenia	8	0
Thrombocytopenic purpura	1	0
Thrombotic thrombocytopenic purpura	3	0
Blood disorders SOC TOTAL	123	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	34	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	2	1
Cardiac failure acute	1	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	2	0
Angina pectoris	2	0
Myocardial infarction	8	5
Myocardial ischaemia	3	2
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Myocardial disorders NEC</i>		
Left ventricular hypertrophy	1	1
<i>Noninfectious pericarditis</i>		
Pericarditis	5	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	6	0
Extrasystoles	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	25	0
Tachycardia paroxysmal	3	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	6	0
Sinus tachycardia	1	0
Supraventricular tachycardia	3	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	4	2
Ventricular fibrillation	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	117	13

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Congenital disorders NEC</i>		
Multiple congenital abnormalities	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Talipes	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital musculoskeletal anomaly	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	2	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	3	0
Ear discomfort	4	0
Ear pain	11	0
Ear swelling	3	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>Hearing losses</i>		
Deafness	5	0
Deafness neurosensory	3	0
Deafness unilateral	2	0
Hypoacusis	4	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	9	0
Vertigo	16	0
Vertigo positional	3	0
Ear disorders SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Endocrine disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival oedema	1	0
Conjunctivitis allergic	1	0
<i>Eyelid movement disorders</i>		
Eyelid function disorder	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Uveitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Chalazion	1	0
Eyelid irritation	1	0
Eyelid oedema	1	0
Swelling of eyelid	10	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid thickening	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	14	0
Eye swelling	22	0
Eyelid pain	2	0
Periorbital oedema	4	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye inflammation	3	0
Eye irritation	4	0
Eye pruritus	7	0
Ocular hyperaemia	4	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	6	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	2	0
Photophobia	9	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Pupil disorders</i>		
Pupil fixed	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal tear	1	0
<i>Visual disorders NEC</i>		
Diplopia	3	0
Metamorphopsia	1	0
Photopsia	5	0
Vision blurred	13	0
<i>Visual field disorders</i>		
Visual field defect	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	5	0
Blindness transient	2	0
Blindness unilateral	1	0
Visual impairment	9	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	165	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis acute	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal erythema	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	78	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	28	0
Abdominal pain lower	1	0
Abdominal pain upper	23	0
Abdominal rigidity	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	10	0
Dysphagia	14	0
Odynophagia	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	163	0
Retching	4	0
Vomiting	139	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	12	0
Lip dry	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Salivary hypersecretion	2	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Lip blister	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	9	0
Lip erythema	1	0
Lip pain	2	0
Oral discomfort	3	0
Oral mucosal blistering	4	0
Oral mucosal eruption	1	0
Oral mucosal erythema	1	0
Oral pain	3	0
Oral pruritus	2	0
Paraesthesia oral	43	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	42	0
Mouth swelling	8	0
Oedema mouth	1	0
Salivary gland infections and inflammations		
Salivary duct inflammation	1	0
Stomatitis and ulceration		
Aphthous ulcer	1	0
Mouth ulceration	5	0
Stomatitis	1	0
Tongue disorders		
Glossitis	2	0
Plicated tongue	1	0
Tongue disorder	2	0
Tongue ulceration	1	0
Tongue signs and symptoms		
Glossodynia	1	0
Swollen tongue	31	0
Tongue discolouration	1	0
Tongue discomfort	1	0
Tongue eruption	1	0
Tongue erythema	1	0
Tongue oedema	1	0
Tongue pruritus	1	0
Gastrointestinal disorders SOC TOTAL	681	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site joint movement impairment	2	0
Administration site nerve damage	1	0
Administration site pain	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site joint pain	1	0
Application site pain	4	0
Application site pruritus	1	0
Application site rash	1	0
Application site swelling	1	0
Application site vesicles	1	0
<i>Asthenic conditions</i>		
Asthenia	61	0
Chronic fatigue syndrome	2	0
Fatigue	174	0
Malaise	243	0
Sluggishness	1	0
<i>Complications associated with device NEC</i>		
Injury associated with device	2	0
<i>Death and sudden death</i>		
Brain death	1	1
Death	9	9
Sudden death	8	8
<i>Febrile disorders</i>		
Pyrexia	286	0
<i>Feelings and sensations NEC</i>		
Chills	104	0
Feeling abnormal	35	0
Feeling cold	19	0
Feeling drunk	2	0
Feeling hot	86	0
Feeling jittery	1	0
Feeling of body temperature change	12	0
Sensation of foreign body	2	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	4	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	13	1
Crepitations	1	0
Crying	1	0
Disease recurrence	1	0
Effusion	1	0
General physical health deterioration	1	0
Ill-defined disorder	1	0
Illness	18	0
Induration	7	0
Influenza like illness	135	0
Local reaction	38	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Multiple organ dysfunction syndrome	2	0
Peripheral swelling	118	0
Screaming	1	0
Secretion discharge	2	0
Swelling	93	0
Swelling face	48	0
Inflammations		
Granuloma	24	0
Inflammation	31	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Injection site reactions		
Injected limb mobility decreased	7	0
Injection site abscess sterile	1	0
Injection site bruising	5	0
Injection site discomfort	3	0
Injection site erythema	82	0
Injection site extravasation	1	0
Injection site fibrosis	1	0
Injection site hypersensitivity	1	0
Injection site hypertrophy	1	0
Injection site induration	6	0
Injection site inflammation	28	0
Injection site joint pain	1	0
Injection site joint warmth	1	0
Injection site mass	11	0
Injection site movement impairment	2	0
Injection site necrosis	2	0
Injection site oedema	1	0
Injection site pain	70	0
Injection site pruritus	24	0
Injection site rash	14	0
Injection site reaction	104	0
Injection site swelling	34	0
Injection site urticaria	4	0
Injection site vesicles	7	0
Injection site warmth	18	0
Interactions		
Drug interaction	10	0
Inhibitory drug interaction	1	0
Potentiating drug interaction	1	0
Mass conditions NEC		
Mass	9	0
Necrosis NEC		
Necrosis	2	0
Oedema NEC		
Face oedema	2	0
Generalised oedema	2	0
Oedema	6	0
Oedema peripheral	9	0
Pain and discomfort NEC		
Axillary pain	12	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Chest discomfort	31	0
Chest pain	29	0
Discomfort	3	0
Facial pain	7	0
Non-cardiac chest pain	1	0
Pain	149	0
Tenderness	18	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	14	1
Adverse event	1	0
Adverse reaction	1	0
Drug ineffective	3	0
Immediate post-injection reaction	1	0
Vaccination failure	12	0
<i>Ulcers NEC</i>		
Ulcer	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	5	0
Shoulder injury related to vaccine administration	5	0
Vaccination site atrophy	1	0
Vaccination site bruising	19	0
Vaccination site discharge	1	0
Vaccination site discolouration	4	0
Vaccination site discomfort	6	0
Vaccination site erythema	148	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	4	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	19	0
Vaccination site inflammation	35	0
Vaccination site irritation	2	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	4	0
Vaccination site joint pain	2	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	28	0
Vaccination site movement impairment	11	0
Vaccination site necrosis	1	0
Vaccination site pain	159	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	34	0
Vaccination site rash	28	0
Vaccination site reaction	10	0
Vaccination site swelling	148	0
Vaccination site urticaria	2	0
Vaccination site vesicles	1	0
Vaccination site warmth	83	0
General disorders SOC TOTAL	3141	20

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Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Hepatitis cholestatic	1	0
Jaundice	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic failure and associated disorders</i>		
Hepatorenal syndrome	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	83	0
Type III immune complex mediated reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	3	0
Reaction to excipient	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	99	1
Anaphylactic shock	8	0
Anaphylactoid reaction	5	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	2	0
Immune-mediated adverse reaction	2	0
Sensitisation	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Kidney transplant rejection	1	0
Immune system disorders SOC TOTAL	213	1

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diarrhoea infectious	1	0
Gastroenteritis	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Cellulitis	25	0
Folliculitis	1	0
Gangrene	2	0
Injection site cellulitis	4	0
Pneumonia bacterial	1	0
Vaccination site cellulitis	11	0
<i>Bone and joint infections</i>		
Vaccination site joint infection	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
<i>Candida infections</i>		
Candida infection	2	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	16	1
Meningitis	2	0
Myelitis	3	0
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	4	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
Hordeolum	2	0
<i>Herpes viral infections</i>		
Herpes ophthalmic	1	0
Herpes simplex	2	0
Herpes simplex encephalitis	1	0
Herpes zoster	11	0
Ophthalmic herpes zoster	2	0
Oral herpes	3	0
<i>Infections NEC</i>		
Abscess	6	0
Device related infection	1	0
Infection	5	0
Injection site abscess	8	0
Injection site infection	2	0
Localised infection	1	0
Respiratory tract infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	2	0
<i>Infectious transmissions</i>		
Infection via vaccinee	1	0

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Infections Infections cont'd		
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	33	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	17	0
Lower respiratory tract infection	23	0
Pneumonia	17	5
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	8	2
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Impetigo	1	0
Pustule	1	0
Skin infection	1	0
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
Streptococcal abscess	1	0
<i>Tuberculous infections</i>		
Erythema induratum	5	0
<i>Upper respiratory tract infections</i>		
Laryngitis	2	0
Nasopharyngitis	20	0
Pharyngitis	2	0
Rhinitis	8	0
Sinusitis	9	0
Tonsillitis	1	0
Upper respiratory tract infection	6	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Pyelonephritis	1	0
Urinary tract infection	1	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Encephalitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	3	0
Vestibular neuronitis	1	0
Viral infection	4	0
Viral rash	1	0
Viral upper respiratory tract infection	6	0
Infections SOC TOTAL	320	8

Case Series Drug Analysis Print

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Report Run Date: 17-Aug-2021
Earliest Reaction Date: 09-Oct-1963

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Cerebral injuries NEC</i>		
Brain herniation	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	4	0
Maternal exposure during pregnancy	6	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	8	0
Product use issue	2	0
Wrong technique in product usage process	3	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Ligament sprain	1	0
Muscle injury	1	0
Muscle rupture	1	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
Wound	1	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
Wound decomposition	1	0
Wound dehiscence	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
<i>Product administration errors and issues</i>		
Accidental underdose	1	0
Contraindicated product administered	1	0
Extra dose administered	3	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	1	0
Incorrect route of product administration	2	0
Product administered at inappropriate site	15	0
Product administered to patient of inappropriate age	1	0
Product administration error	2	0
Wrong product administered	2	0
<i>Product monitoring errors and issues</i>		
Documented hypersensitivity to administered product	1	0

Case Series Drug Analysis Print

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DAP**

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Skin injuries NEC</i>		
Contusion	29	0
Scar	3	0
Skin abrasion	1	0
Skin laceration	2	0
<i>Vaccination related complications</i>		
Vaccination complication	2	0
Injuries SOC TOTAL	117	0

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Reaction Name	Total	Fatal
Investigations		
Autoimmunity analyses		
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody positive	1	0
Rheumatoid factor increased	1	0
Blood gas and acid base analyses		
Oxygen saturation decreased	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose increased	1	0
Chemistry analyses NEC		
Inflammatory marker increased	1	0
Coagulation and bleeding analyses		
Bleeding time prolonged	1	0
Coagulation time prolonged	2	0
International normalised ratio decreased	1	0
International normalised ratio increased	10	0
ECG investigations		
Electrocardiogram abnormal	1	0
Haematological analyses NEC		
Red blood cell sedimentation rate increased	8	0
Heart rate and pulse investigations		
Heart rate decreased	4	0
Heart rate increased	19	0
Heart rate irregular	6	0
Pulse abnormal	3	0
Liver function analyses		
Alanine aminotransferase increased	4	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	2	0
Liver function test abnormal	5	0
Liver function test increased	1	0
Microbiology and serology tests NEC		
Blood culture negative	1	0
Mineral and electrolyte analyses		
Blood sodium abnormal	1	0
Neurologic diagnostic procedures		
Electroencephalogram abnormal	2	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	17	0
Grip strength decreased	2	0
Respiratory rate increased	4	0
Weight decreased	3	0
Weight increased	4	0
Platelet analyses		
Platelet count decreased	4	0
Protein analyses NEC		
C-reactive protein	1	0
C-reactive protein abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
C-reactive protein increased	3	0
Red blood cell analyses		
Haemoglobin decreased	1	0
Mean cell volume increased	1	0
Reproductive hormone analyses		
Blood testosterone decreased	1	0
Respiratory and pulmonary function diagnostic procedures		
Total lung capacity decreased	1	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray abnormal	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	3	0
Thyroid analyses		
Thyroid function test abnormal	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Urinalysis NEC		
Blood urine present	3	0
Glucose urine present	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	6	0
Blood pressure increased	14	0
Blood pressure systolic decreased	1	0
White blood cell analyses		
Lymphocyte morphology abnormal	1	0
Neutrophil count decreased	2	0
White blood cell count decreased	2	0
White blood cell count increased	2	0
Investigations SOC TOTAL	166	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	44	0
<i>Cell metabolism disorders NEC</i>		
Mitochondrial cytopathy	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	4	0
Feeding disorder	1	0
Food aversion	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	2	0
Hypoglycaemia neonatal	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	62	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	9	0
Arthritis allergic	1	0
Arthropathy	9	0
Polyarthritits	3	0
Seronegative arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	5	0
Spinal pain	1	0
<i>Bursal disorders</i>		
Bursitis	4	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	9	0
<i>Joint related disorders NEC</i>		
Periarthritis	16	0
Rotator cuff syndrome	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	172	0
Joint effusion	2	0
Joint noise	2	0
Joint range of motion decreased	3	0
Joint stiffness	10	0
Joint swelling	19	0
<i>Muscle infections and inflammations</i>		
Myositis	6	0
<i>Muscle pains</i>		
Myalgia	164	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	4	0
Muscle discomfort	1	0
Muscle fatigue	2	0
Muscle mass	1	0
Muscle spasms	19	0
Muscle swelling	1	0
Muscle tightness	7	0
Muscle twitching	6	0
Neuropathic muscular atrophy	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	47	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	8	0
Muscle contracture	1	0
Musculoskeletal stiffness	56	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
Winged scapula	2	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Back pain	44	0
Limb discomfort	24	0
Musculoskeletal chest pain	4	0
Musculoskeletal discomfort	3	0
Musculoskeletal pain	1	0
Neck pain	42	0
Pain in extremity	221	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	3	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	6	0
Soft tissue disorders NEC		
Axillary mass	2	0
Groin pain	2	0
Neck mass	2	0
Spondyloarthropathies		
Arthritis reactive	4	0
Tendon disorders		
Tendon pain	1	0
Tendonitis	3	0
Tenosynovitis	1	0
Muscle & tissue disorders SOC TOTAL	968	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	1
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Neurofibrosarcomas</i>		
Neurofibrosarcoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	6	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Hyporeflexia	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	4	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	43	1
<i>Autonomic nervous system disorders</i>		
Autonomic failure syndrome	1	0
Horner's syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	5	0
Ischaemic stroke	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
Lumbosacral radiculoplexus neuropathy	1	0
<i>Coma states</i>		
Coma	3	0
<i>Coordination and balance disturbances</i>		
Ataxia	4	0
Balance disorder	15	0
Coordination abnormal	2	0
Dysstasia	3	0
Nystagmus	4	0
<i>Cortical dysfunction NEC</i>		
Aphasia	15	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	4	1
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Depressed level of consciousness	5	0
Lethargy	37	0
Loss of consciousness	31	0
Somnolence	26	0
Stupor	1	0
Syncope	88	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	9	0
Hypokinesia	6	0
Movement disorder	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	4	0
Posterior reversible encephalopathy syndrome	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	11	0
Facial paralysis	9	0
Facial paresis	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	8	0
Headaches NEC		
Cluster headache	1	0
Headache	286	0
Sinus headache	2	0
Tension headache	3	0
Hydrocephalic conditions		
Hydrocephalus	2	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Intracranial pressure increased	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	2	0
Memory loss (excl dementia)		
Amnesia	2	0
Memory impairment	3	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	2	0
Disturbance in attention	8	0
Mental impairment	1	0
Migraine headaches		
Migraine	18	0
Ophthalmic migraine	1	0
Mononeuropathies		
Mononeuropathy multiplex	1	0
Motor neurone diseases		
Motor neurone disease	1	1
Multiple sclerosis acute and progressive		
Multiple sclerosis	5	0
Muscle tone abnormal		
Hypotonia	3	0
Myelitis (incl infective)		
Myelitis transverse	7	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	4	0
Narcolepsy	3	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Nervous system disorder	6	0
Neurologic visual problems NEC		
Hemianopia homonymous	1	0
Neurological signs and symptoms NEC		
Dizziness	226	0
Dizziness postural	2	0
Head discomfort	6	0
Meningism	6	0
Neurological symptom	2	0
Presyncope	19	0
Unresponsive to stimuli	13	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Olfactory nerve disorders</i>		
Anosmia	2	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	7	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	18	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	10	0
Hypoaesthesia	79	0
Paraesthesia	149	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	5	0
Hemiplegia	1	0
Monoparesis	1	0
Monoplegia	2	0
Paralysis	6	0
Paraparesis	2	0
Paraplegia	1	0
Quadriparesis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Cogwheel rigidity	1	0
Freezing phenomenon	1	0
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	3	0
Brachial plexopathy	2	0
Neuralgic amyotrophy	6	0
Neuritis	1	0
Neuropathy peripheral	15	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	14	0
Epileptic aura	1	0
Febrile convulsion	1	0
Partial seizures	3	0
Seizure	37	0
Seizure like phenomena	2	0
Status epilepticus	2	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	6	0
Dysgeusia	14	0
Electric shock sensation	4	0
Hypogeusia	1	0
Neuralgia	15	0
Restless legs syndrome	1	0
Sensory disturbance	9	0
Sensory loss	7	0
Taste disorder	5	0
<i>Speech and language abnormalities</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Dysarthria	10	0
Incoherent	2	0
Speech disorder	6	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculitis brachial	4	0
Structural brain disorders NEC		
Brain injury	1	0
Transient cerebrovascular events		
Transient ischaemic attack	2	0
Tremor (excl congenital)		
Tremor	41	0
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	1505	3

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	15	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
Prolonged labour	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
Stillbirth	2	2
Pregnancy conditions SOC TOTAL	21	3

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Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Device malfunction	1	0
Oversensing	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	2	0
<i>Product physical issues</i>		
Product colour issue	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
null SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	12	0
Nervousness	3	0
Stress	1	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
<i>Confusion and disorientation</i>		
Confusional state	27	0
Disorientation	16	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	11	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	22	0
Middle insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	5	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Phonophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	5	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	3	0
Feeling of despair	1	0
Tearfulness	4	0
<i>Mood disorders NEC</i>		
Apathy	1	0
<i>Panic attacks and disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Panic attack	2	0
Panic reaction	1	0
<i>Parasomnias</i>		
Abnormal dreams	3	0
Nightmare	3	0
Rapid eye movements sleep abnormal	1	0
<i>Perception disturbances NEC</i>		
Derealisation	1	0
Illusion	1	0
Near death experience	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	6	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	1	0
Thinking abnormal	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	164	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder spasm	1	0
Dysuria	3	0
Incontinence	3	0
Micturition urgency	1	0
Pollakiuria	1	0
Urinary incontinence	2	0
Urinary retention	3	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Bladder obstruction	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	3	0
<i>Renal disorders NEC</i>		
Single functional kidney	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Anuria	1	0
Chronic kidney disease	1	0
Renal failure	5	0
Renal impairment	3	0
<i>Urethral infections and inflammations</i>		
Urethritis noninfective	1	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	41	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Breast swelling	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal disorder	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Vulval ulceration	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal pain	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	13	0

Case Series Drug Analysis Print

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Report Run Date: 17-Aug-2021
Earliest Reaction Date: 09-Oct-1963

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	101	0
Dyspnoea exertional	1	0
Hyperventilation	2	0
Hypopnoea	2	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	1	0
Respiratory depression	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	29	0
Bronchospasm	5	0
Chronic obstructive pulmonary disease	6	2
Status asthmaticus	1	0
Wheezing	27	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	1	0
<i>Coughing and associated symptoms</i>		
Cough	59	0
Haemoptysis	4	0
Productive cough	8	0
Sputum increased	3	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Pneumonia aspiration	1	0
Pneumonitis	4	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	16	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	10	0
<i>Newborn respiratory disorders NEC</i>		
Bronchopulmonary dysplasia	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	3	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	1	0
Interstitial lung disease	1	0
Lung infiltration	1	0
Pulmonary fibrosis	8	2
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoesthesia	1	0
Pharyngeal paraesthesia	4	0
Pharyngeal swelling	17	0
Pharyngeal ulceration	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tonsillar hypertrophy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	4	2
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	6	2
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	2	0
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Lung disorder	2	0
Respiratory disorder	5	0
Respiratory tract inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	5	0
Catarrh	1	0
Choking	1	0
Choking sensation	1	0
Dry throat	3	0
Dysphonia	11	0
Nasal discomfort	4	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	69	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	30	0
Sinus pain	4	0
Sneezing	16	0
Snoring	1	0
Throat irritation	6	0
Throat tightness	24	0
Upper respiratory tract congestion	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	540	8

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	2	0
<i>Angioedemas</i>		
Angioedema	11	0
Circumoral oedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	28	0
Hyperhidrosis	80	0
Miliaria	2	0
Night sweats	9	0
<i>Bullous conditions</i>		
Blister	14	0
Blood blister	4	0
Erythema multiforme	9	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	2	0
<i>Connective tissue disorders</i>		
Dermatomyositis	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	5	0
Pain of skin	6	0
Papule	2	0
Scab	1	0
Scar pain	1	0
Skin burning sensation	4	0
Skin discolouration	7	0
Skin disorder	1	0
Skin induration	3	0
Skin lesion	5	0
Skin reaction	19	0
Skin sensitisation	2	0
Skin swelling	2	0
Skin texture abnormal	4	0
Skin tightness	3	0
Skin warm	37	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	7	0
Dermatitis allergic	19	0
Dermatitis contact	1	0
Eczema	7	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	191	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Palmar erythema	1	0
Exfoliative conditions		
Dermatitis exfoliative	1	0
Skin exfoliation	11	0
Nail and nail bed conditions (excl infections and infestations)		
Onychoclasia	1	0
Papulosquamous conditions		
Lichen planus	2	0
Pityriasis rosea	5	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	2	0
Pilar disorders NEC		
Hair colour changes	1	0
Pruritus NEC		
Pruritus	170	0
Psoriatic conditions		
Psoriasis	3	0
Purpura and related conditions		
Henoch-Schonlein purpura	6	0
Petechiae	5	0
Purpura	13	0
Pustular conditions		
Rash follicular	1	0
Rashes, eruptions and exanthems NEC		
Rash	180	0
Rash erythematous	36	0
Rash macular	18	0
Rash maculo-papular	8	0
Rash papular	13	0
Rash pruritic	30	0
Rash vesicular	4	0
Scaly conditions		
Pityriasis	1	0
Skin and subcutaneous conditions NEC		
Skin mass	2	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin dystrophies		
Keloid scar	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin injuries and mechanical dermatoses		
Needle track marks	1	0
Skin vasculitides		
Cutaneous vasculitis	5	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	5	0
Skin vasomotor conditions		
Livedo reticularis	1	0
Urticarias		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria	105	0
Urticaria chronic	1	0
Urticarial vasculitis	2	0
Skin disorders SOC TOTAL	1142	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	4	0
Immobile	3	0
Impaired work ability	4	0
Loss of personal independence in daily activities	5	0
Physical disability	1	0
Walking disability	1	0
<i>Social issues NEC</i>		
Contraindication to vaccination	1	0
Social circumstances SOC TOTAL	19	0

Case Series Drug Analysis Print

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DAP

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
Surgical & medical procedures SOC TOTAL	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm rupture	1	1
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	12	1
Peripheral circulatory failure	1	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	4	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Vasospasm	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	7	0
Flushing	32	0
Hot flush	13	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	9	0
Peripheral ischaemia	2	0
Poor peripheral circulation	1	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	34	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Hypotension	13	0
<i>Vasculitides NEC</i>		
Granulomatosis with polyangiitis	3	0
Microscopic polyangiitis	1	0
Polyarteritis nodosa	1	1
Vasculitis	17	0
Vascular disorders SOC TOTAL	171	3
TOTAL REACTIONS FOR DRUG	9793	62
TOTAL REPORTS	3478	
TOTAL FATAL OUTCOME REPORTS		62