

## Case Series Drug Analysis Print

**Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine**

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

FOI 21/590 - All UK suspected, spontaneous adverse drug  
Pneumococcal reactions reports associated with the Pneumococcal  
Polysaccharide Polysaccharide vaccine until 08/04/2021  
Vaccine:

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	3	0
<b><i>Anaemias haemolytic NEC</i></b>		
Haemolytic anaemia	1	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	1	0
Coombs positive haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Increased tendency to bruise	1	0
<b><i>Coagulopathies</i></b>		
Factor VIII inhibition	1	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	2	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	2	0
<b><i>Leukocytoses NEC</i></b>		
Neutrophilia	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	4	0
Lymphadenitis	3	0
Lymphadenopathy	44	0
Lymphadenopathy mediastinal	1	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplastic anaemia	1	0
Pancytopenia	1	0
<b><i>Neutropenias</i></b>		
Agranulocytosis	1	0
Febrile neutropenia	1	0
Neutropenia	1	0
<b><i>Sickle cell trait and disorders</i></b>		
Sickle cell anaemia with crisis	3	0
<b><i>Spleen disorders</i></b>		
Splenomegaly	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	3	0
Thrombocytopenia	3	0
<b>Blood disorders SOC TOTAL</b>	<b>80</b>	<b>0</b>

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<b>Cardiac disorders</b>		
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	10	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	1	0
Coronary artery thrombosis	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure acute	1	1
Ventricular failure	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	2	0
Angina pectoris	3	0
Myocardial infarction	5	3
Myocardial ischaemia	4	1
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Myocardial disorders NEC</b></i>		
Myocardial fibrosis	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	1	0
<i><b>Pericardial disorders NEC</b></i>		
Cardiac tamponade	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	1	0
Bradycardia	3	0
Cardiac flutter	1	0
Tachycardia	17	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	3	0
Sinus tachycardia	1	0
Supraventricular tachycardia	2	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>65</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Haemoglobinopathies congenital</i>		
Sickle cell anaemia	1	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear disorder	1	0
Ear pain	5	0
<i>Eustachian tube disorders</i>		
Eustachian tube dysfunction	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness neurosensory	1	0
Deafness unilateral	1	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	7	0
Vertigo	11	0
<b>Ear disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	2	0
<b>Endocrine disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	2	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Uveitis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Swelling of eyelid	1	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Dacryostenosis acquired	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye oedema	1	0
Eye pain	2	0
Eye swelling	2	0
Periorbital oedema	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye discharge	1	0
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	2	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	10	0
<i><b>Orbital structural change, deposit and degeneration</b></i>		
Orbital oedema	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Necrotising retinitis	1	0
<i><b>Scleral infections, irritations and inflammations</b></i>		
Scleritis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	2	0
Photopsia	1	0
Vision blurred	7	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Visual acuity reduced	2	0
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>47</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	1
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	46	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	10	0
Abdominal pain lower	2	0
Abdominal pain upper	9	0
Abdominal tenderness	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Duodenogastric reflux	1	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Anal incontinence	1	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	185	0
Retching	1	0
Vomiting	111	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Lip erythema	1	0
Lip pain	1	0
Oral mucosal blistering	1	0
Oral pain	2	0
Paraesthesia oral	1	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	5	0
Mouth swelling	1	0
Palatal oedema	1	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	1	0
<b><i>Peritoneal and retroperitoneal haemorrhages</i></b>		
Retroperitoneal haematoma	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	5	0
Stomatitis	2	0
<b><i>Tongue disorders</i></b>		
Glossitis	1	0
Tongue ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	3	0
Tongue blistering	2	0
Tongue oedema	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>442</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Administration site rash	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	67	0
Chronic fatigue syndrome	2	0
Fatigue	121	0
Malaise	282	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	2	2
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	468	0
<i>Feelings and sensations NEC</i>		
Chills	181	0
Feeling abnormal	15	0
Feeling cold	28	0
Feeling drunk	1	0
Feeling hot	65	0
Feeling of body temperature change	15	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	2	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Foaming at mouth	1	0
Ill-defined disorder	1	0
Illness	14	0
Induration	12	0
Influenza like illness	103	0
Local reaction	176	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	362	0
Screaming	1	0
Swelling	112	0
Swelling face	7	0
<i>Inflammations</i>		
Inflammation	71	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	5	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	9	0
Injection site abscess sterile	1	0
Injection site atrophy	1	0
Injection site bruising	2	0
Injection site discharge	1	0

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<b>General disorders</b> General disorders cont'd		
Injection site discolouration	3	0
Injection site erythema	85	0
Injection site haematoma	2	0
Injection site haemorrhage	1	0
Injection site hypersensitivity	1	0
Injection site induration	9	0
Injection site inflammation	73	0
Injection site joint swelling	1	0
Injection site joint warmth	1	0
Injection site mass	11	0
Injection site movement impairment	3	0
Injection site necrosis	3	0
Injection site oedema	4	0
Injection site pain	100	0
Injection site pruritus	8	0
Injection site rash	20	0
Injection site reaction	118	0
Injection site scar	3	0
Injection site swelling	74	0
Injection site ulcer	3	0
Injection site urticaria	3	0
Injection site vesicles	3	0
Injection site warmth	25	0
<b>Interactions</b>		
Drug interaction	4	0
Inhibitory drug interaction	1	0
<b>Mass conditions NEC</b>		
Mass	6	0
Nodule	1	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		
Localised oedema	9	0
Oedema	13	0
Oedema peripheral	14	0
<b>Pain and discomfort NEC</b>		
Axillary pain	16	0
Chest discomfort	25	0
Chest pain	28	0
Discomfort	7	0
Facial pain	3	0
Non-cardiac chest pain	1	0
Pain	193	0
Tenderness	33	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse event	1	0
Drug ineffective	9	0
Therapeutic response decreased	1	0
Therapy non-responder	6	0
<b>Ulcers NEC</b>		
Ulcer	2	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	5	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site erythema	80	0
Vaccination site haematoma	1	0
Vaccination site induration	16	0
Vaccination site inflammation	19	0
Vaccination site irritation	3	0
Vaccination site joint effusion	1	0
Vaccination site joint movement impairment	4	0
Vaccination site joint pain	1	0
Vaccination site joint swelling	1	0
Vaccination site mass	9	0
Vaccination site movement impairment	21	0
Vaccination site necrosis	1	0
Vaccination site oedema	1	0
Vaccination site pain	153	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	5	0
Vaccination site rash	19	0
Vaccination site reaction	14	0
Vaccination site scab	1	0
Vaccination site swelling	90	0
Vaccination site vesicles	1	0
Vaccination site warmth	48	0
<b>General disorders SOC TOTAL</b>	<b>3592</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	1	0
Cholelithiasis	2	0
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	3	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	1
Hepatic failure	1	0
Hepatorenal syndrome	2	0
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	1	1
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatitis	2	0
Hepatitis chronic active	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>17</b>	<b>2</b>

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<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	51	0
Multiple allergies	1	0
Serum sickness	1	0
Serum sickness-like reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	13	0
Anaphylactic shock	6	1
Anaphylactoid reaction	3	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<i><b>Blood isoimmune reactions</b></i>		
Alloimmunisation	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Immune system disorder	2	0
<i><b>Vasculitides</b></i>		
Eosinophilic granulomatosis with polyangiitis	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>85</b>	<b>1</b>

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<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Administration site cellulitis	3	0
Arthritis bacterial	2	0
Bacterial infection	1	0
Bacterial sepsis	1	0
Cellulitis	145	0
Cellulitis gangrenous	1	0
Injection site cellulitis	29	0
Pneumonia bacterial	1	0
Post procedural cellulitis	1	0
Vaccination site cellulitis	22	0
<i><b>Bone and joint infections</b></i>		
Arthritis infective	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	5	0
Encephalomyelitis	1	0
Meningitis	1	0
Myelitis	1	0
<i><b>Clostridia infections</b></i>		
Clostridium difficile infection	1	0
Gas gangrene	1	1
<i><b>Dental and oral soft tissue infections</b></i>		
Parotitis	1	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
Labyrinthitis	1	0
Otitis media	2	0
Otitis media acute	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	1	0
<i><b>Haemophilus infections</b></i>		
Haemophilus infection	1	0
Haemophilus sepsis	1	0
Septic arthritis haemophilus	1	0
<i><b>Herpes viral infections</b></i>		
Herpes zoster	9	0
Varicella zoster virus infection	1	0
<i><b>Infections NEC</b></i>		
Abscess	6	0
Abscess limb	2	0
Infection	9	0
Injection site abscess	2	0
Injection site infection	1	0
Localised infection	4	0
Respiratory tract infection	3	0
Systemic infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	3	0
<i><b>Influenza viral infections</b></i>		
Influenza	10	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	6	0
Lower respiratory tract infection	16	0

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<b>Infections</b>		
Infections cont'd		
Pneumonia	31	8
<b>Male reproductive tract infections</b>		
Orchitis	1	0
<b>Neisseria infections</b>		
Meningitis meningococcal	1	0
Meningococcal sepsis	1	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Bacteraemia	1	0
Sepsis	11	0
Septic shock	2	0
<b>Skin structures and soft tissue infections</b>		
Carbuncle	1	0
Skin infection	2	0
Subcutaneous abscess	1	0
<b>Streptococcal infections</b>		
Bronchitis pneumococcal	1	0
Erysipelas	1	0
Meningitis pneumococcal	7	0
Pneumococcal infection	5	0
Pneumococcal sepsis	1	1
Pneumonia pneumococcal	1	0
Pneumonia streptococcal	1	1
Streptococcal sepsis	1	0
<b>Tuberculous infections</b>		
Erythema induratum	9	0
<b>Upper respiratory tract infections</b>		
Laryngitis	2	0
Nasopharyngitis	15	0
Rhinitis	1	0
Upper respiratory tract infection	1	0
<b>Urinary tract infections</b>		
Urinary tract infection	3	0
<b>Vascular infections</b>		
Lymphangitis	4	0
<b>Viral infections NEC</b>		
Gastroenteritis viral	1	0
Post viral fatigue syndrome	2	0
Vestibular neuronitis	1	0
Viral infection	1	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>412</b>	<b>11</b>

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<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	3	0
Foetal exposure during pregnancy	2	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Circumstance or information capable of leading to medication error	1	0
Medication error	3	0
Product use in unapproved indication	1	0
Product use issue	1	0
Vaccination error	1	0
Wrong technique in product usage process	2	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	1	0
<i><b>Non-site specific procedural complications</b></i>		
Wound decomposition	1	0
<i><b>Off label uses</b></i>		
Off label use	3	0
<i><b>Product administration errors and issues</b></i>		
Extra dose administered	2	0
Inappropriate schedule of product administration	6	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	4	0
Product administered to patient of inappropriate age	1	0
Product administration error	5	0
Wrong product administered	2	0
<i><b>Product prescribing errors and issues</b></i>		
Product prescribing error	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	19	0
Scar	2	0
<i><b>Vaccination related complications</b></i>		
Vaccination complication	4	0
Vaccination failure	10	0
<b>Injuries SOC TOTAL</b>	<b>77</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody positive	1	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Streptococcus test positive	2	0
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen saturation decreased	5	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose decreased	1	0
Blood glucose fluctuation	1	0
Blood glucose increased	2	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	1	0
<b><i>Cell marker analyses</i></b>		
Prostatic specific antigen increased	1	0
<b><i>Chemistry analyses NEC</i></b>		
Inflammatory marker increased	2	0
<b><i>Cholesterol analyses</i></b>		
High density lipoprotein decreased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Fibrin D dimer increased	1	0
International normalised ratio increased	2	0
<b><i>Haematological analyses NEC</i></b>		
Red blood cell sedimentation rate increased	2	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate increased	15	0
Heart rate irregular	2	0
<b><i>Immunoglobulin analyses</i></b>		
Blood immunoglobulin G decreased	1	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test abnormal	1	0
Antibody test negative	2	0
<b><i>Investigations NEC</i></b>		
Blood test abnormal	1	0
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
<b><i>Microbiology and serology tests NEC</i></b>		
Seroconversion test negative	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood potassium increased	1	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
X-ray limb abnormal	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature abnormal	2	0
Body temperature fluctuation	3	0
Body temperature increased	50	0
Grip strength decreased	1	0
Weight decreased	4	0
<b><i>Platelet analyses</i></b>		
Platelet count decreased	4	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	4	0
<b><i>Red blood cell analyses</i></b>		

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### Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Haematocrit abnormal	1	0
Red blood cell count decreased	1	0
<b>Renal function analyses</b>		
Blood creatinine increased	2	0
<b>Skeletal and cardiac muscle analyses</b>		
Blood creatine phosphokinase increased	2	0
<b>Urinalysis NEC</b>		
Blood urine present	3	0
Protein urine present	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output decreased	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	2	0
Blood pressure decreased	4	0
Blood pressure increased	5	0
<b>White blood cell analyses</b>		
Eosinophil count increased	1	0
Neutrophil count increased	1	0
White blood cell count increased	6	0
<b>Investigations SOC TOTAL</b>	<b>147</b>	<b>0</b>

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### Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	71	0
Hypophagia	1	0
Increased appetite	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	6	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	2	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	3	0
Feeding disorder	3	0
Food aversion	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	5	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>100</b>	<b>0</b>

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### Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	5	0
Arthropathy	3	0
Polyarthritis	6	0
Seronegative arthritis	1	0
<b><i>Bone disorders NEC</i></b>		
Jaw disorder	1	0
Osteonecrosis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	4	0
Bone swelling	1	0
Pain in jaw	2	0
<b><i>Bursal disorders</i></b>		
Bursitis	5	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	1	0
<b><i>Connective tissue disorders NEC</i></b>		
Myofascitis	1	0
Polymyalgia rheumatica	8	0
<b><i>Joint related disorders NEC</i></b>		
Joint lock	1	0
Periarthritis	12	0
Rotator cuff syndrome	1	0
Temporomandibular joint syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	143	0
Joint effusion	2	0
Joint range of motion decreased	1	0
Joint stiffness	6	0
Joint swelling	24	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Systemic lupus erythematosus	1	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	6	0
<b><i>Muscle pains</i></b>		
Myalgia	135	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle disorder	1	0
Muscle fatigue	5	0
Muscle mass	1	0
Muscle spasms	13	0
Muscle swelling	2	0
Muscle tightness	1	0
Muscle twitching	2	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	32	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Limb mass	1	0
Mobility decreased	9	0
Musculoskeletal stiffness	53	0
Weight bearing difficulty	29	0

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	29	0
Limb discomfort	18	0
Musculoskeletal chest pain	5	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	18	0
Pain in extremity	366	0
<i>Myopathies</i>		
Myopathy	1	0
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	7	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Soft tissue disorder	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	2	0
<i>Synovial disorders</i>		
Synovitis	1	0
<i>Tendon disorders</i>		
Tendon disorder	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>981</b>	<b>0</b>

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>Breast and nipple neoplasms malignant</b></i>		
Intraductal proliferative breast lesion	1	0
Invasive ductal breast carcinoma	1	0
<i><b>Leukaemias NEC</b></i>		
Leukaemia	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	2	1
<i><b>Mesotheliomas malignant and unspecified</b></i>		
Mesothelioma	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to bone	1	0
<i><b>Non-small cell neoplasms malignant of the respiratory tract cell type specified</b></i>		
Lung adenocarcinoma stage IV	1	1
<b>Neoplasms SOC TOTAL</b>	<b>8</b>	<b>2</b>

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Report Run Date: 29-Jun-2021

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	15	2
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	7	2
<i>Choreiform movements</i>		
Choreoathetosis	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Diabetic neuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	12	0
Coordination abnormal	1	0
Dysstasia	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
Primary progressive aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	2	1
<i>Disturbances in consciousness NEC</i>		
Lethargy	40	0
Loss of consciousness	16	0
Somnolence	30	0
Stupor	2	0
Syncope	29	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	10	0
Movement disorder	4	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
Facial paresis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	226	0
Sinus headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	3	0
Disturbance in attention	6	0
<i>Migraine headaches</i>		
Migraine	7	0
<i>Mononeuropathies</i>		
Nerve compression	1	0
Peroneal nerve palsy	1	0
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	2	0
<i>Myelitis (incl infective)</i>		

## Case Series Drug Analysis Print

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Myelitis transverse	1	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	2	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	3	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	1	0
Visual field defect	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	89	0
Dizziness postural	4	0
Head discomfort	2	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	6	0
Slow response to stimuli	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	2	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	13	0
Hyperaesthesia	3	0
Hypoaesthesia	31	0
Paraesthesia	45	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	2	0
Hemiplegia	1	0
Monoplegia	9	0
Paralysis	3	0
<b>Parkinson's disease and parkinsonism</b>		
Cogwheel rigidity	1	0
Parkinson's disease	1	0
<b>Peripheral neuropathies NEC</b>		
Brachial plexopathy	1	0
Neuralgic amyotrophy	2	0
Neuritis	2	0
Neuropathy peripheral	1	0
Polyneuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	4	0
Febrile convulsion	1	0
Seizure	9	0
Status epilepticus	1	0
<b>Sensory abnormalities NEC</b>		
Allodynia	1	0
Dysgeusia	2	0
Neuralgia	4	0
Sensory disturbance	6	0
Sensory loss	2	0
Taste disorder	2	0
<b>Speech and language abnormalities</b>		
Dysarthria	5	0
Slow speech	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Speech disorder	4	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	4	0
Radiculopathy	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	37	0
<b>Nervous system disorders SOC TOTAL</b>	<b>751</b>	<b>5</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
<i>Maternal complications of delivery NEC</i>		
Complication of delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>6</b>	<b>0</b>

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MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Product contamination and sterility issues</i></b>		
Product contamination microbial	1	0
<b><i>Product quality issues NEC</i></b>		
Product quality issue	2	0
<b>null SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	3	0
Tension	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Paranoia	1	0
Social avoidant behaviour	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	10	0
Disorientation	8	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	5	0
<b><i>Depressive disorders</i></b>		
Depression	4	0
<b><i>Dissociative states</i></b>		
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	25	0
<b><i>Eating disorders NEC</i></b>		
Binge eating	1	0
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Irritability	3	0
Mood altered	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	5	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressive symptom	1	0
Tearfulness	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	4	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	1	0
Nightmare	2	0
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	1	0
<b><i>Psychotic disorder NEC</i></b>		
Psychotic disorder	2	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	8	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>98</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>		
Dysuria	4	0
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	4	0
Urinary incontinence	3	0
Urinary retention	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder obstruction	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis rapidly progressive	1	0
Nephrotic syndrome	3	0
<i><b>Nephritis NEC</b></i>		
Lupus nephritis	1	0
Tubulointerstitial nephritis	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	7	0
Chronic kidney disease	2	0
<i><b>Urinary abnormalities</b></i>		
Haematuria	1	0
Proteinuria	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Polyuria	1	0
Renal pain	3	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>37</b>	<b>0</b>

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	1	0
Breast mass	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast pain	4	0
Breast swelling	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital rash	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular disorder	1	0
<i><b>Vaginal and vulval infections and inflammations</b></i>		
Vulvovaginal inflammation	2	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vulval ulceration	2	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vulvovaginal burning sensation	1	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	1	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	57	0
Dyspnoea exertional	1	0
Hyperventilation	2	0
Respiratory arrest	1	0
Respiratory distress	2	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchiectasis	4	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	15	2
Bronchospasm	4	0
Wheezing	15	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	62	0
Haemoptysis	2	0
Productive cough	8	0
Sputum discoloured	2	0
Sputum increased	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pulmonary eosinophilia	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Increased bronchial secretion	4	0
Pleuritic pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Emphysema	1	0
Organising pneumonia	1	0
Pulmonary fibrosis	8	2
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	2	0
Tonsillar inflammation	1	0
<i><b>Pleural conditions NEC</b></i>		
Pleural thickening	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	6	0
Pneumothorax	1	0
<i><b>Pulmonary oedemas</b></i>		
Acute pulmonary oedema	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	1	1
<i><b>Respiratory tract disorders NEC</b></i>		
Lung disorder	1	0
Respiratory tract congestion	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	1	0
Catarrh	3	0
Dysphonia	3	0

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Nasal discomfort	1	0
Oropharyngeal pain	25	0
Rhinorrhoea	9	0
Sneezing	6	0
Throat irritation	2	0
Throat tightness	4	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>270</b>	<b>5</b>

## Case Series Drug Analysis Print

### Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	64	0
Miliaria	1	0
Night sweats	10	0
<i>Bullous conditions</i>		
Blister	6	0
Erythema multiforme	2	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	5	0
Pain of skin	8	0
Scab	1	0
Sensitive skin	3	0
Skin burning sensation	3	0
Skin discolouration	6	0
Skin disorder	1	0
Skin induration	17	0
Skin lesion	3	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin reaction	14	0
Skin sensitisation	1	0
Skin swelling	2	0
Skin tightness	3	0
Skin warm	46	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	4	0
Dermatitis allergic	10	0
Dermatitis contact	1	0
Eczema	4	0
Skin irritation	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	339	0
<i>Exfoliative conditions</i>		
Skin exfoliation	7	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail atrophy	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pilar disorders NEC</i>		
Hair disorder	1	0

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Report Run Date: 29-Jun-2021

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Earliest Reaction Date: 23-Nov-1979

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Hair texture abnormal	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	48	0
<i><b>Psoriatic conditions</b></i>		
Erythrodermic psoriasis	1	0
Guttate psoriasis	1	0
Psoriasis	1	0
<i><b>Purpura and related conditions</b></i>		
Henoch-Schonlein purpura	4	0
Petechiae	3	0
Purpura	2	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	72	0
Rash erythematous	26	0
Rash macular	23	0
Rash maculo-papular	3	0
Rash papular	10	0
Rash pruritic	9	0
<i><b>Sebaceous gland disorders</b></i>		
Fordyce spots	1	0
<i><b>Skin dystrophies</b></i>		
Skin wrinkling	2	0
<i><b>Skin hypoplasias and atrophies</b></i>		
Skin striae	1	0
<i><b>Skin injuries and mechanical dermatoses</b></i>		
Needle track marks	2	0
<i><b>Skin vasculitides</b></i>		
Vasculitic rash	5	0
<i><b>Urticarias</b></i>		
Urticaria	59	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>859</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	4	0
Immobile	2	0
Loss of personal independence in daily activities	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	2	0
<b>Social circumstances SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Report Run Date: 29-Jun-2021

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MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Inner ear therapeutic procedures</i>		
Cochlea implant	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Medical device removal	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>6</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21/590 - Pneumococcal Polysaccharide Vaccine

Report Run Date: 29-Jun-2021  
 Earliest Reaction Date: 23-Nov-1979

Data Lock Date: 08-Apr-2021 19:00:04  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	11	1
Shock	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	1	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	1
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	5	0
Flushing	14	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	11	0
<i>Site specific vascular disorders NEC</i>		
Pallor	11	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	7	0
<i>Vascular hypotensive disorders</i>		
Hypotension	16	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Granulomatosis with polyangiitis	1	0
Vasculitis	5	0
Vasculitis necrotising	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>93</b>	<b>2</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>8238</b>	<b>38</b>
<b>TOTAL REPORTS</b>	<b>2583</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>38</b>