

## Case Series Drug Analysis Print

**Name: Pneumococcal Conjugate Vaccine**

Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Pneumococcal UK Spontaneous ADR Reactions for PCV until  
Conjugate Vaccine: 31/01/2021.

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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 immune</i></b>		
Autoimmune haemolytic anaemia	1	0
<b><i>Anaemias haemolytic mechanical factor</i></b>		
Haemolytic uraemic syndrome	5	0
<b><i>Haematological disorders</i></b>		
Mastocytosis	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	1	0
<b><i>Leukocytoses NEC</i></b>		
Lymphocytic infiltration	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Abdominal lymphadenopathy	1	0
Lymphadenitis	1	0
Lymphadenopathy	3	0
<b><i>Neutropenias</i></b>		
Febrile neutropenia	1	0
Neutropenia	1	0
<b><i>Sickle cell trait and disorders</i></b>		
Sickle cell anaemia with crisis	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	2	0
Thrombocytopenia	5	0
<b>Blood disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
Cardiovascular disorder	3	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	2	0
Pericardial haemorrhage	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Bradycardia	17	0
Bradycardia neonatal	1	0
Tachycardia	17	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	13	5
Cardio-respiratory arrest	3	1
Ventricular fibrillation	1	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>65</b>	<b>6</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital nystagmus	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	3	0
Ear swelling	5	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	5	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
<b>Ear disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	1	0
<i><b>Eyelid movement disorders</b></i>		
Excessive eye blinking	4	0
Eyelid ptosis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	2	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Erythema of eyelid	1	0
Eyelid oedema	1	0
Swelling of eyelid	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye oedema	2	0
Eye swelling	16	0
Periorbital oedema	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	19	0
Gaze palsy	2	0
Strabismus	3	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Photophobia	3	0
<i><b>Orbital structural change, deposit and degeneration</b></i>		
Lid sulcus deepened	1	0
<i><b>Pupil disorders</b></i>		
Miosis	2	0
Mydriasis	4	0
Pupil fixed	2	0
Pupils unequal	2	0
<i><b>Visual disorders NEC</b></i>		
Photopsia	1	0
Vision blurred	2	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	2	0
Cortical visual impairment	1	0
Visual impairment	3	0
<b>Eye disorders SOC TOTAL</b>	<b>82</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Necrotising colitis	2	1
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	164	0
Diarrhoea haemorrhagic	2	0
Diarrhoea neonatal	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	10	0
Faecaloma	1	0
Faeces discoloured	12	0
Faeces hard	1	0
Faeces pale	1	0
Faeces soft	2	0
Mucous stools	9	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
Flatulence	8	0
<i>Gastritis (excl infective)</i>		
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	13	0
Abdominal pain upper	16	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	10	0
Gastrooesophageal reflux disease	10	0
Intestinal dilatation	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Necrotising enterocolitis neonatal	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Dysphagia	1	0
Gastrointestinal wall thickening	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	6	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Inguinal hernias</i>		
Inguinal hernia, obstructive	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	4	0
Nausea	14	0
Regurgitation	1	0
Vomiting	222	0
Vomiting projectile	15	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematemesis	1	0
Haematochezia	13	0
<b><i>Oral dryness and saliva altered</i></b>		
Salivary hypersecretion	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Lip pain	1	0
Oral pain	1	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	12	0
Mouth swelling	2	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	1	0
<b><i>Tongue disorders</i></b>		
Tongue disorder	1	0
Tongue geographic	1	0
<b><i>Tongue signs and symptoms</i></b>		
Protrusion tongue	2	0
Swollen tongue	3	0
Tongue blistering	1	0
Tongue discolouration	2	0
Tongue movement disturbance	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>601</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Application and instillation site reactions</b></i>		
Application site irritation	1	0
Application site papules	1	0
<i><b>Asthenic conditions</b></i>		
Asthenia	15	0
Decreased activity	3	0
Fatigue	19	0
Malaise	91	0
<i><b>Body temperature altered</b></i>		
Hyperthermia	1	0
Hypothermia	2	0
<i><b>Death and sudden death</b></i>		
Brain death	1	0
Death	19	19
Sudden death	6	6
Sudden infant death syndrome	10	10
<i><b>Febrile disorders</b></i>		
Hyperpyrexia	1	0
Pyrexia	528	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	15	0
Feeling abnormal	17	0
Feeling cold	4	0
Feeling drunk	1	0
Feeling hot	37	0
Thirst	4	0
Thirst decreased	3	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	12	0
Gait inability	10	0
Loss of control of legs	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	9	0
Crepitations	1	0
Crying	189	0
Developmental delay	5	0
Effusion	1	0
Foaming at mouth	1	0
General physical health deterioration	2	0
Glassy eyes	5	0
High-pitched crying	17	0
Illness	10	0
Induration	16	0
Influenza like illness	3	0
Irritability postvaccinal	3	0
Local reaction	64	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	99	0
Pneumatosis	1	0
Screaming	93	0
Secretion discharge	3	0
Swelling	75	0

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<b>General disorders</b> General disorders cont'd		
Swelling face	21	0
<b>Inflamations</b>		
Inflammation	35	0
Systemic inflammatory response syndrome	2	0
<b>Injection site reactions</b>		
Injection site bruising	6	0
Injection site cyst	1	0
Injection site discharge	1	0
Injection site discolouration	5	0
Injection site erosion	1	0
Injection site erythema	133	0
Injection site hypersensitivity	1	0
Injection site induration	14	0
Injection site inflammation	42	0
Injection site irritation	1	0
Injection site joint erythema	1	0
Injection site mass	32	0
Injection site movement impairment	1	0
Injection site oedema	3	0
Injection site pain	25	0
Injection site pruritus	1	0
Injection site rash	13	0
Injection site reaction	65	0
Injection site swelling	109	0
Injection site urticaria	5	0
Injection site vesicles	4	0
Injection site warmth	26	0
<b>Mass conditions NEC</b>		
Cyst	1	0
Mass	6	0
<b>Oedema NEC</b>		
Face oedema	2	0
Localised oedema	2	0
Oedema	3	0
Oedema peripheral	16	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	3	0
Chest pain	1	0
Discomfort	13	0
Pain	56	0
Tenderness	19	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse reaction	1	0
Drug ineffective	145	0
Immediate post-injection reaction	1	0
Therapeutic product ineffective	223	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	3	0
Vaccination site bruising	5	0
Vaccination site discomfort	1	0
Vaccination site erythema	46	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site haematoma	2	0
Vaccination site haemorrhage	1	0
Vaccination site induration	17	0
Vaccination site inflammation	9	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	23	0
Vaccination site movement impairment	1	0
Vaccination site pain	24	0
Vaccination site pruritus	2	0
Vaccination site rash	8	0
Vaccination site reaction	5	0
Vaccination site scab	1	0
Vaccination site swelling	35	0
Vaccination site urticaria	1	0
Vaccination site vesicles	2	0
Vaccination site warmth	13	0
<b>General disorders SOC TOTAL</b>	<b>2645</b>	<b>35</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Jaundice cholestatic	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergy to metals	1	0
Hypersensitivity	39	0
Multiple allergies	2	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	1	0
Drug hypersensitivity	1	0
Food allergy	3	0
Milk allergy	6	0
Reaction to excipient	1	0
Rubber sensitivity	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	31	1
Anaphylactic shock	2	0
Anaphylactoid reaction	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Decreased immune responsiveness	1	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	2	0
Sensitisation	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	3	0
<b>Immune system disorders SOC TOTAL</b>	<b>102</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Gastroenteritis	2	0
<i><b>Bacterial infections NEC</b></i>		
Arthritis bacterial	3	0
Bacterial infection	1	0
Bacterial sepsis	2	0
Cellulitis	32	0
Injection site cellulitis	4	0
Meningitis bacterial	3	0
Pyomyositis	1	0
Skin bacterial infection	3	0
Vaccination site cellulitis	6	0
<i><b>Bone and joint infections</b></i>		
Intervertebral discitis	1	0
<i><b>Bordetella infections</b></i>		
Pertussis	2	0
<i><b>Candida infections</b></i>		
Candida infection	1	0
Oral candidiasis	3	0
<i><b>Cardiac infections</b></i>		
Endocarditis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Cavernous sinus thrombosis	1	0
Encephalitis	6	1
Meningitis	13	0
Meningitis aseptic	7	0
Subdural abscess	1	0
<i><b>Coxsackie viral infections</b></i>		
Hand-foot-and-mouth disease	1	0
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	1	0
<i><b>Ear infections</b></i>		
Ear infection	8	0
Mastoiditis	3	0
Otitis media	4	0
<i><b>Enteroviral infections NEC</b></i>		
Meningitis enteroviral	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	6	0
Eye infection	1	0
<i><b>Haemophilus infections</b></i>		
Haemophilus sepsis	1	0
<i><b>Herpes viral infections</b></i>		
Herpes virus infection	1	0
Herpes zoster	1	0
Oral herpes	1	0
Varicella	1	0
<i><b>Infections NEC</b></i>		
Abscess	2	0
Abscess limb	1	0
Empyema	62	0
Febrile infection	1	0
Infection	7	0

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<b>Infections</b>		
Infections cont'd		
Injection site abscess	3	0
Injection site infection	3	0
Localised infection	1	0
Vaccination site abscess	4	0
Vaccination site infection	3	0
<b><i>Influenza viral infections</i></b>		
Influenza	3	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	4	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	24	0
Pneumonia	46	0
Pneumonia necrotising	1	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Neisseria infections</i></b>		
Meningococcal infection	2	0
Meningococcal sepsis	1	0
<b><i>Parainfluenzae viral infections</i></b>		
Parainfluenzae virus infection	1	0
<b><i>Respiratory syncytial viral infections</i></b>		
Respiratory syncytial virus bronchiolitis	4	0
Respiratory syncytial virus infection	1	0
<b><i>Rhinoviral infections</i></b>		
Rhinovirus infection	1	0
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	1	0
<b><i>Salmonella infections</i></b>		
Salmonellosis	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Bacteraemia	14	0
Sepsis	35	0
Septic shock	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Eczema infected	1	0
Skin infection	2	0
<b><i>Staphylococcal infections</i></b>		
Staphylococcal infection	1	0
Staphylococcal sepsis	1	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	45	2
Pharyngitis streptococcal	1	0
Pneumococcal bacteraemia	17	0
Pneumococcal infection	325	11
Pneumococcal sepsis	25	2
Pneumonia pneumococcal	21	1
Pneumonia streptococcal	2	0
Septic arthritis streptococcal	1	0
Streptococcal bacteraemia	1	0
Streptococcal sepsis	2	0
<b><i>Upper respiratory tract infections</i></b>		

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Croup infectious	4	0
Nasopharyngitis	12	0
Pharyngitis	1	0
Rhinitis	8	0
Tonsillitis	6	0
Upper respiratory tract infection	11	0
<b>Urinary tract infections</b>		
Kidney infection	1	0
Urinary tract infection	3	0
<b>Viral infections NEC</b>		
Bronchiolitis	8	0
Gastroenteritis viral	1	0
Viral infection	5	0
Viral upper respiratory tract infection	3	0
<b>Infections SOC TOTAL</b>	<b>861</b>	<b>17</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Maternal exposure during breast feeding	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	2	0
Wrong technique in product usage process	2	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle injury	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Injury	1	0
Wound secretion	2	0
<i><b>Product administration errors and issues</b></i>		
Extra dose administered	1	0
Inappropriate schedule of product administration	10	0
Incomplete course of vaccination	1	0
Incorrect dose administered	1	0
Incorrect route of product administration	2	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	5	0
Product administration error	4	0
Wrong product administered	1	0
<i><b>Product prescribing errors and issues</b></i>		
Product prescribing error	1	0
Product prescribing issue	1	0
<i><b>Product storage errors and issues in the product use system</b></i>		
Product storage error	2	0
<i><b>Skin injuries NEC</b></i>		
Contusion	14	0
Scar	1	0
Scratch	1	0
Skin injury	1	0
Skin laceration	1	0
<i><b>Vaccination related complications</b></i>		
Post vaccination syndrome	1	0
Vaccination complication	3	0
Vaccination failure	22	0
<b>Injuries SOC TOTAL</b>	<b>84</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Streptococcus test positive	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	20	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose fluctuation	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>Central nervous system histopathology procedures</b></i>		
Biopsy brain abnormal	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF white blood cell count increased	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	2	0
<i><b>Coagulation and bleeding analyses</b></i>		
Coagulation test abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate abnormal	2	0
Heart rate decreased	2	0
Heart rate increased	12	0
Pulse abnormal	1	0
<i><b>Immunology analyses NEC</b></i>		
Antibody test abnormal	2	0
Antibody test negative	2	0
Tryptase increased	1	0
<i><b>Metabolism tests NEC</b></i>		
Blood ketone body increased	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood magnesium decreased	1	0
Blood sodium decreased	2	0
<i><b>Ophthalmic function diagnostic procedures</b></i>		
Intraocular pressure increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature abnormal	4	0
Body temperature decreased	3	0
Body temperature fluctuation	3	0
Body temperature increased	65	0
Breath sounds abnormal	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	3	0
Weight decreased	3	0
<i><b>Platelet analyses</b></i>		
Platelet count increased	3	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	17	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	3	0
<i><b>Renal function analyses</b></i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	1	0

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### Name: Pneumococcal Conjugate Vaccine

Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
White blood cells urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Capillary nail refill test abnormal	1	0
<i>Virus identification and serology</i>		
Coronavirus test positive	1	0
<i>White blood cell analyses</i>		
Eosinophil count increased	1	0
Lymphocyte count increased	1	0
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
White blood cell count increased	5	0
<b>Investigations SOC TOTAL</b>	<b>184</b>	<b>0</b>

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	2	0
Decreased appetite	87	0
Food refusal	2	0
Hypophagia	6	0
<b><i>Cell metabolism disorders NEC</i></b>		
Mitochondrial cytopathy	1	0
<b><i>Chloride imbalance</i></b>		
Hyperchloraemia	1	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	2	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	1	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Dairy intolerance	3	0
Food intolerance	3	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	1	0
Failure to thrive	1	0
Feeding disorder	6	0
Food aversion	4	0
Poor feeding infant	52	0
Weight gain poor	4	0
<b><i>Hypoglycaemic conditions NEC</i></b>		
Hypoglycaemia	1	0
<b><i>Metabolic acidoses (excl diabetic acidoses)</i></b>		
Metabolic acidosis	3	0
<b><i>Potassium imbalance</i></b>		
Hyperkalaemia	1	0
<b><i>Sodium imbalance</i></b>		
Hyponatraemia	2	0
<b><i>Sugar intolerance (excl glucose intolerance)</i></b>		
Lactose intolerance	2	0
<b><i>Total fluid volume decreased</i></b>		
Dehydration	5	0
<b>Metabolic disorders SOC TOTAL</b>	<b>190</b>	<b>0</b>

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Polyarthritis	1	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	2	0
Periarthritis	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	11	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint swelling	4	0
Joint warmth	1	0
<i><b>Muscle pains</b></i>		
Myalgia	7	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle disorder	1	0
Muscle spasms	3	0
Muscle tightness	1	0
Muscle twitching	8	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	31	0
Muscle rigidity	7	0
Trismus	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	2	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Limb mass	1	0
Musculoskeletal stiffness	17	0
Posture abnormal	2	0
Toe walking	1	0
Weight bearing difficulty	10	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Limb discomfort	5	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	2	0
Pain in extremity	51	0
<i><b>Tendon disorders</b></i>		
Tendonitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>176</b>	<b>0</b>

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Earliest Reaction Date: 21-Sep-2001

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	2	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Astrocytoma	1	0
<i>Rhabdomyosarcomas</i>		
Rhabdomyosarcoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
<b>Neoplasms SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Report Run Date: 11-Feb-2021

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	10	0
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebral infarction	1	0
Intraventricular haemorrhage	1	0
Ruptured cerebral aneurysm	1	0
<b><i>Cerebrovascular venous and sinus thrombosis</i></b>		
Superior sagittal sinus thrombosis	1	0
<b><i>Coordination and balance disturbances</i></b>		
Balance disorder	4	0
Coordination abnormal	1	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
Nystagmus	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	4	0
Dyspraxia	2	0
Sensory processing disorder	2	0
<b><i>Disturbances in consciousness NEC</i></b>		
Depressed level of consciousness	6	0
Lethargy	54	0
Loss of consciousness	16	0
Sedation	1	0
Somnolence	74	0
Syncope	16	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Dyskinesia	26	0
Fine motor delay	1	0
Hypokinesia	3	0
Motor dysfunction	1	0
Movement disorder	3	0
Psychomotor hyperactivity	3	0
<b><i>Dystonias</i></b>		
Dystonia	1	0
Opisthotonus	3	0
<b><i>Encephalopathies NEC</i></b>		
Hypoxic-ischaemic encephalopathy	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	15	0
<b><i>Headaches NEC</i></b>		
Headache	10	0
Tension headache	1	0
<b><i>Hydrocephalic conditions</i></b>		
Hydrocephalus	2	0
<b><i>Increased intracranial pressure disorders</i></b>		
Brain oedema	3	0
<b><i>Intellectual disabilities</i></b>		
Intellectual disability	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	2	0
Disturbance in attention	3	0
<b><i>Muscle tone abnormal</i></b>		
Hypertonia	1	0

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Earliest Reaction Date: 21-Sep-2001

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Hypotonia	67	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	11	0
<b><i>Nervous system disorders NEC</i></b>		
Brain stem syndrome	1	0
Nervous system disorder	4	0
Subdural effusion	3	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Cerebrospinal fluid leakage	1	0
Dizziness	7	0
Dizziness postural	1	0
Drooling	2	0
Exaggerated startle response	2	0
Fontanelle bulging	6	0
Grimacing	1	0
Hypo-responsive to stimuli	5	0
Inability to crawl	1	0
Infant irritability	2	0
Meningism	1	0
Myoclonus	1	0
Neurological decompensation	1	0
Neurological symptom	1	0
Pleocytosis	3	0
Presyncope	4	0
Unresponsive to stimuli	66	0
<b><i>Neuromuscular disorders NEC</i></b>		
Hypotonic-hypo-responsive episode	10	0
Muscle spasticity	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	2	0
Hyperaesthesia	2	0
Hypoaesthesia	2	0
Paraesthesia	3	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paralysis	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	9	0
Epileptic encephalopathy	1	0
Febrile convulsion	48	0
Infantile spasms	1	0
Partial seizures	9	0
Seizure	79	0
Seizure anoxic	1	0
Seizure cluster	2	0
Seizure like phenomena	1	0
Status epilepticus	3	0
<b><i>Sensory abnormalities NEC</i></b>		
Restless legs syndrome	1	0
Sensory disturbance	1	0
<b><i>Sleep disturbances NEC</i></b>		
Poor quality sleep	5	0
Sleep deficit	1	0
<b><i>Speech and language abnormalities</i></b>		



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Speech disorder	3	0
Speech disorder developmental	3	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculopathy	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	24	0
<b>Nervous system disorders SOC TOTAL</b>	<b>682</b>	<b>0</b>

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Newborn complications NEC</i>		
Neonatal disorder	4	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>

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MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Needle issue	2	0
<i>Product quality issues NEC</i>		
Product quality issue	4	0
<b>null SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	21	0
Behaviour disorder	1	0
Breath holding	11	0
Regressive behaviour	1	0
Staring	10	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	1	0
<b><i>Affect alterations NEC</i></b>		
Flat affect	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	9	0
Anxiety	4	0
Stress	1	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Disturbance in social behaviour	1	0
Personality change	4	0
Social avoidant behaviour	1	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	1	0
Disorientation	3	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	1	0
Insomnia	21	0
Middle insomnia	3	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	3	0
Selective eating disorder	5	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	30	0
Emotional poverty	1	0
Irritability	155	0
Mood altered	6	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear of eating	1	0
Social fear	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	5	0
Hallucination, auditory	1	0
Hallucinations, mixed	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	29	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	3	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	5	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Tearfulness	1	0
<b>Mood disorders NEC</b>		
Apathy	1	0
Listless	9	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive-compulsive symptom	1	0
<b>Parasomnias</b>		
Sleep terror	4	0
<b>Personality disorders with anxious behaviour (Cluster C)</b>		
Dependent personality disorder	1	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	14	0
<b>Psychiatric elimination disorders</b>		
Enuresis	1	0
<b>Psychiatric symptoms NEC</b>		
Decreased eye contact	4	0
<b>Sleep disorders NEC</b>		
Sleep disorder	17	0
<b>Somatic symptom disorders</b>		
Conversion disorder	1	0
<b>Speech articulation and rhythm disturbances</b>		
Lack of spontaneous speech	1	0
<b>Stereotypies and automatisms</b>		
Head banging	3	0
<b>Suicidal and self-injurious behaviour</b>		
Self-injurious ideation	1	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>408</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Anuria	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Urine abnormality	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	35	0
Apnoeic attack	7	0
Dyspnoea	47	0
Grunting	5	0
Hyperventilation	1	0
Hypopnoea	9	0
Hypoventilation	2	0
Irregular breathing	1	0
Respiration abnormal	2	0
Respiratory arrest	18	0
Respiratory distress	9	0
Tachypnoea	8	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Wheezing	25	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Cyanosis central	1	0
Hypoxia	2	1
Respiratory acidosis	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	41	0
Haemoptysis	1	0
Productive cough	6	0
Sputum discoloured	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	3	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pleuritic pain	1	0
Pulmonary haemorrhage	3	1
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	2	0
<i><b>Neonatal hypoxic conditions</b></i>		
Infantile apnoea	5	0
Neonatal hypoxia	3	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	3	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	6	0
Pharyngeal swelling	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	16	0
Pneumothorax	3	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Acute respiratory failure	1	1
Respiratory failure	1	0
<b><i>Respiratory signs and symptoms NEC</i></b>		
Use of accessory respiratory muscles	1	0
<b><i>Respiratory tract disorders NEC</i></b>		
Lung disorder	1	1
Respiratory disorder	5	0
<b><i>Tracheal disorders (excl infections and neoplasms)</i></b>		
Tracheal disorder	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Choking	5	0
Dysphonia	3	0
Nasal discomfort	1	0
Nasal obstruction	1	0
Oropharyngeal pain	10	0
Rhinorrhoea	17	0
Sneezing	1	0
Throat irritation	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>328</b>	<b>4</b>

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Earliest Reaction Date: 21-Sep-2001

Data Lock Date: 03-Feb-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Angioedemas</i></b>		
Angioedema	4	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	11	0
Hyperhidrosis	17	0
<b><i>Bullous conditions</i></b>		
Blister	15	0
Dermatitis bullous	1	0
Erythema multiforme	9	0
Pemphigoid	3	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	7	0
Macule	1	0
Pain of skin	4	0
Papule	6	0
Scab	1	0
Skin burning sensation	3	0
Skin discolouration	36	0
Skin discomfort	1	0
Skin disorder	3	0
Skin induration	3	0
Skin lesion	5	0
Skin odour abnormal	1	0
Skin plaque	1	0
Skin reaction	12	0
Skin tightness	4	0
Skin warm	29	0
Yellow skin	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	1	0
Dermatitis allergic	17	0
Dermatitis atopic	2	0
Dermatitis diaper	7	0
Eczema	17	0
Eczema infantile	1	0
Eczema weeping	1	0
Skin irritation	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	282	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	3	0
<b><i>Pruritus NEC</i></b>		
Pruritus	23	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	1	0
Petechiae	34	0
Purpura	20	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash	261	0
Rash erythematous	36	0
Rash macular	71	0
Rash maculo-papular	16	0
Rash morbilliform	14	0
Rash papular	24	0
Rash pruritic	6	0
Rash rubelliform	2	0
Rash vesicular	3	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	4	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	21	0
<b><i>Urticarias</i></b>		
Urticaria	110	0
Urticaria pigmentosa	1	0
Urticaria pressure	1	0
<b>Skin disorders SOC TOTAL</b>	<b>1162</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Pneumococcal Conjugate Vaccine

Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	2	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Pneumococcal Conjugate Vaccine

Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Inner ear therapeutic procedures</i>		
Cochlea implant	1	0
<i>Therapeutic procedures NEC</i>		
Medical device removal	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: Pneumococcal Conjugate Vaccine

Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Aneurysms and dissections non-site specific</b></i>		
Aneurysm	1	0
<i><b>Arterial infections and inflammations</b></i>		
Kawasaki's disease	1	1
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	7	0
Hypoperfusion	1	0
Shock	5	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	1	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Venous thrombosis	1	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Fibromuscular dysplasia	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Capillary fragility	1	0
Superficial vein prominence	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	37	0
Flushing	9	0
Hot flush	3	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	8	0
Poor peripheral circulation	2	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	122	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>203</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>7856</b>	<b>65</b>
<b>TOTAL REPORTS</b>	<b>2731</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>65</b>