

Case Series Drug Analysis Print

Name: PCV

Report Run Date: 21-Feb-2014
Data Lock Date: 19-Feb-2014 23:39:39
Earliest Reaction Date: 21-Sep-2001
MedDRA Version: MedDRA 16.1
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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Anaemias haemolytic mechanical factor</i>		
Haemolytic uraemic syndrome	2	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	1	0
<i>Thrombocytopenias</i>		
Idiopathic thrombocytopenic purpura	1	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	22	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	11	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	5	4
Cardiac disorders SOC TOTAL	42	4

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Haemoglobinopathies congenital</i>		
Sickle cell anaemia with crisis	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital nystagmus	1	0
Congenital disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	1	0
Ear disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis	2	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	3	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	1	0
<i>Ocular disorders NEC</i>		
Eye oedema	1	0
Eye swelling	9	0
Periorbital oedema	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	12	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	1	0
Pupil fixed	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	38	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	86	0
Diarrhoea haemorrhagic	1	0
Diarrhoea neonatal	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	4	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	5	0
Abdominal pain upper	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Regurgitation	1	0
Vomiting	113	0
Vomiting projectile	4	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	3	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	5	0
Oedema mouth	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
Swollen tongue	2	0
Tongue blistering	1	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	247	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site papules	1	0
<i>Asthenic conditions</i>		
Asthenia	6	0
Fatigue	4	0
Malaise	45	0
<i>Death and sudden death</i>		
Death	5	5
Sudden death	1	1
Sudden infant death syndrome	3	3
<i>Febrile disorders</i>		
Pyrexia	167	0
<i>Feelings and sensations NEC</i>		
Chills	2	0
Feeling abnormal	5	0
Feeling cold	1	0
Feeling hot	22	0
Thirst	1	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Abasia	2	0
Gait disturbance	4	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	85	0
Foaming at mouth	1	0
Glassy eyes	1	0
Induration	11	0
Influenza like illness	1	0
Irritability	60	0
Irritability postvaccinal	1	0
Local reaction	61	0
Local swelling	82	0
Swelling	38	0
<i>Inflammations</i>		
Inflammation	30	0
<i>Injection site reactions</i>		
Injection site bruising	6	0
Injection site cyst	1	0
Injection site discharge	1	0
Injection site discolouration	3	0
Injection site erosion	1	0
Injection site erythema	118	0
Injection site hypersensitivity	1	0
Injection site induration	13	0
Injection site inflammation	37	0
Injection site irritation	1	0
Injection site joint redness	1	0
Injection site mass	27	0
Injection site movement impairment	1	0
Injection site oedema	2	0
Injection site pain	21	0
Injection site pruritus	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site rash	10	0
Injection site reaction	64	0
Injection site swelling	96	0
Injection site urticaria	4	0
Injection site vesicles	3	0
Injection site warmth	21	0
Mass conditions NEC		
Cyst	1	0
Mass	2	0
Oedema NEC		
Extensive swelling of vaccinated limb	1	0
Face oedema	2	0
Localised oedema	2	0
Oedema	2	0
Oedema peripheral	15	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	1	0
Discomfort	5	0
Pain	15	0
Tenderness	17	0
Therapeutic and nontherapeutic responses		
Adverse reaction	1	0
Drug ineffective	95	0
Therapeutic product ineffective	99	0
Vaccination site reactions		
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site reaction	2	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	1339	9

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
Hepatic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	19	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Milk allergy	2	0
Rubber sensitivity	1	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	12	1
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immunisation reaction	2	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	42	1

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	4	0
Cellulitis	13	0
Injection site cellulitis	4	0
Meningitis bacterial	1	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
Osteomyelitis	1	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Meningitis	4	0
Subdural empyema	1	0
<i>Ear infections</i>		
Ear infection	2	0
Mastoiditis	1	0
Otitis media	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis infective	1	0
<i>Haemophilus infections</i>		
Haemophilus sepsis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
Oral herpes	1	0
<i>Infections NEC</i>		
Abscess	2	0
Empyema	29	0
Infection	4	0
Injection site abscess	3	0
Injection site infection	3	0
Vaccination site abscess	2	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lobar pneumonia	1	0
Lower respiratory tract infection	13	0
Pneumonia	18	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Neisseria infections</i>		
Meningococcal infection	2	0
<i>Parainfluenzae viral infections</i>		
Croup infectious	1	0
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus bronchiolitis	3	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Salmonella infections</i>		
Salmonellosis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Bacteraemia	1	0
Sepsis	11	0
<i>Skin structures and soft tissue infections</i>		
Skin infection	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	36	1
Pharyngitis streptococcal	1	0
Pneumococcal bacteraemia	16	0
Pneumococcal infection	157	2
Pneumococcal sepsis	16	1
Pneumonia pneumococcal	7	0
Pneumonia streptococcal	2	0
Streptococcal sepsis	2	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	5	0
Pharyngitis	1	0
Rhinitis	5	0
Upper respiratory tract infection	6	0
<i>Viral infections NEC</i>		
Bronchiolitis	3	0
Viral infection	4	0
Viral upper respiratory tract infection	3	0
Infections SOC TOTAL	406	4

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Reaction Name	Total	Fatal
Injuries		
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Maladministrations</i>		
Drug administered to patient of inappropriate age	1	0
Drug administration error	3	0
Inappropriate schedule of drug administration	4	0
Incorrect dose administered	2	0
Incorrect route of drug administration	1	0
Wrong technique in drug usage process	1	0
<i>Medication errors NEC</i>		
Medication error	2	0
<i>Non-site specific injuries NEC</i>		
Wound secretion	1	0
<i>Skin injuries NEC</i>		
Contusion	7	0
Laceration	1	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Vaccination failure	12	0
Injuries SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Investigations		
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Streptococcus test positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	9	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Coagulation and bleeding analyses</i>		
Coagulation test abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	4	0
<i>Immunology analyses NEC</i>		
Antibody test abnormal	1	0
Tryptase increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood sodium decreased	2	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature increased	33	0
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Weight decreased	3	0
<i>Platelet analyses</i>		
Platelet count increased	2	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
<i>Renal function analyses</i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Aspiration pleural cavity	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<i>White blood cell analyses</i>		
Eosinophil count increased	1	0
White blood cell count decreased	1	0
White blood cell count increased	2	0
Investigations SOC TOTAL	75	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	31	0
Hypophagia	3	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Cow's milk intolerance	1	0
<i>General nutritional disorders NEC</i>		
Failure to thrive	1	0
Feeding disorder	6	0
Feeding disorder neonatal	5	0
Feeding disorder of infancy or early childhood	6	0
Weight gain poor	2	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	2	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	60	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Polyarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint swelling	4	0
Joint warmth	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Floppy infant	7	0
Muscle rigidity	6	0
Trismus	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	2	0
Neck pain	1	0
Pain in extremity	22	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Musculoskeletal stiffness	6	0
Posture abnormal	2	0
Weight bearing difficulty	2	0
Muscle & tissue disorders SOC TOTAL	64	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	0
<i>Rhabdomyosarcomas</i>		
Rhabdomyosarcoma	1	0
Neoplasms SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	2	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral infarction	1	0
Intraventricular haemorrhage	1	0
Cerebrovascular venous and sinus thrombosis		
Superior sagittal sinus thrombosis	1	0
Coordination and balance disturbances		
Balance disorder	2	0
Cortical dysfunction NEC		
Aphasia	1	0
Developmental disorders cognitive		
Autism	2	0
Disturbances in consciousness NEC		
Depressed level of consciousness	3	0
Lethargy	21	0
Loss of consciousness	6	0
Sedation	1	0
Somnolence	24	0
Syncope	10	0
Dyskinesias and movement disorders NEC		
Dyskinesia	7	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
Dystonias		
Dystonia	1	0
Encephalitis NEC		
Encephalitis	3	0
Generalised tonic-clonic seizures		
Grand mal convulsion	3	0
Headaches NEC		
Headache	3	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Muscle tone abnormal		
Hypotonia	38	0
Narcolepsy and hypersomnia		
Hypersomnia	4	0
Nervous system disorders NEC		
Subdural effusion	2	0
Neurological signs and symptoms NEC		
Fontanelle bulging	3	0
Grimacing	1	0
Meningism	1	0
Presyncope	1	0
Unresponsive to stimuli	16	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	3	0
Paraesthesias and dysaesthesias		
Burning sensation	2	0
Seizures and seizure disorders NEC		

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Nervous system disorders		
Nervous system disorders cont'd		
Convulsion	36	0
Epilepsy	4	0
Febrile convulsion	19	0
Partial seizures	4	0
Seizure cluster	1	0
Status epilepticus	1	0
Sensory abnormalities NEC		
Hypoaesthesia	1	0
Restless legs syndrome	1	0
Speech and language abnormalities		
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Radiculopathy	1	0
Tremor (excl congenital)		
Tremor	7	0
Nervous system disorders SOC TOTAL	244	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Newborn complications NEC</i>		
Neonatal disorder	3	0
Pregnancy conditions SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	4	0
Breath holding	4	0
Staring	6	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	2	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
Decreased activity	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	7	0
Middle insomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	12	0
Mood altered	5	0
<i>Increased physical activity levels</i>		
Restlessness	10	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Listless	3	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Perception disturbances</i>		
Hallucination	4	0
<i>Personality disorders with anxious behaviour (Cluster C)</i>		
Dependent personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
Childhood disintegrative disorder	1	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	6	0
<i>Somatoform disorders</i>		
Conversion disorder	1	0
<i>Speech articulation and rhythm disturbances</i>		
Screaming	47	0
<i>Stereotypies and automatisms</i>		
Head banging	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	130	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary retention	1	0
<i>Renal failure and impairment</i>		
Renal failure acute	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Renal & urinary disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	11	0
Apnoeic attack	4	0
Dyspnoea	20	0
Grunting	4	0
Hypopnoea	5	0
Hypoventilation	1	0
Respiratory arrest	11	0
Respiratory distress	3	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Wheezing	12	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	1
<i>Coughing and associated symptoms</i>		
Cough	20	0
Productive cough	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pleuritic pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Neonatal hypoxic conditions</i>		
Apnoea neonatal	2	0
<i>Parenchymal lung disorders NEC</i>		
Lung consolidation	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	4	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	7	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	1
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	1
Respiratory disorder	3	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	3	0
Dysphonia	1	0
Increased upper airway secretion	1	0
Nasal discomfort	1	0
Oropharyngeal pain	3	0

Case Series Drug Analysis Print

Name: PCV

Report Run Date: 21-Feb-2014
Earliest Reaction Date: 21-Sep-2001

Data Lock Date: 19-Feb-2014 23:39:39
MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Rhinorrhoea	7	0
Sneezing	1	0
Throat irritation	1	0
Respiratory disorders SOC TOTAL	144	3

Case Series Drug Analysis Print

Name: PCV

Report Run Date: 21-Feb-2014
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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	0
Swelling face	8	0
Apocrine and eccrine gland disorders		
Cold sweat	4	0
Hyperhidrosis	6	0
Bullous conditions		
Blister	10	0
Erythema multiforme	7	0
Pemphigoid	2	0
Stevens-Johnson syndrome	1	0
Dermal and epidermal conditions NEC		
Dry skin	3	0
Macule	1	0
Pain of skin	1	0
Papule	1	0
Scab	1	0
Skin burning sensation	2	0
Skin discolouration	11	0
Skin discomfort	1	0
Skin disorder	3	0
Skin induration	1	0
Skin lesion	3	0
Skin odour abnormal	1	0
Skin reaction	9	0
Skin tightness	3	0
Skin warm	10	0
Yellow skin	1	0
Dermatitis and eczema		
Dermatitis allergic	8	0
Dermatitis diaper	3	0
Eczema	3	0
Eczema infantile	1	0
Eczema weeping	1	0
Skin irritation	1	0
Erythemas		
Erythema	198	0
Generalised erythema	9	0
Rash erythematous	20	0
Exfoliative conditions		
Skin exfoliation	3	0
Papulosquamous conditions		
Rash papular	8	0
Pruritus NEC		
Pruritus	11	0
Rash pruritic	4	0
Purpura and related conditions		
Petechiae	14	0
Purpura	14	0
Rashes, eruptions and exanthems NEC		
Rash	103	0
Rash generalised	35	0
Rash macular	42	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash maculo-papular	16	0
Rash morbilliform	3	0
Rash vesicular	2	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	7	0
<i>Urticarias</i>		
Urticaria	69	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	670	0

Case Series Drug Analysis Print

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

Case Series Drug Analysis Print

Name: PCV

Report Run Date: 21-Feb-2014
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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Inner ear therapeutic procedures</i>		
Cochlea implant	1	0
<i>Therapeutic procedures NEC</i>		
Medical device removal	1	0
Surgical & medical procedures SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: PCV

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Shock	4	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Superficial vein prominence	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	6	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	55	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	74	0
TOTAL REACTIONS FOR DRUG	3643	21
TOTAL REPORTS	1440	
TOTAL FATAL OUTCOME REPORTS		21