

## Case Series Drug Analysis Print

**Name: DTPa IPV HIB**

Report Run Date: 20-Feb-2014  
Data Lock Date: 18-Feb-2014 01:01:22  
Earliest Reaction Date: 02-Oct-2002  
MedDRA Version: MedDRA 16.1  
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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
Lymphoid tissue hyperplasia	1	0
<i>Thrombocytopenias</i>		
Idiopathic thrombocytopenic purpura	2	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	41	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	7	0
Tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	1
<b>Cardiac disorders SOC TOTAL</b>	<b>56</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Neurological disorders congenital NEC</i>		
Congenital nystagmus	1	0
<i>Persistent foetal circulation disorders</i>		
Patent ductus arteriosus	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid oedema	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye swelling	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	9	0
Strabismus	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
Pupil fixed	1	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal haemorrhage	1	0
<i><b>Visual disorders NEC</b></i>		
Vision blurred	1	0
Visual impairment	4	0
<b>Eye disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	44	0
Diarrhoea haemorrhagic	1	0
Diarrhoea neonatal	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	2	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	3	0
Abdominal pain upper	2	0
Gastrointestinal pain	1	0
Infantile colic	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Nausea and vomiting symptoms</i>		
Infantile spitting up	1	0
Nausea	1	0
Regurgitation	2	0
Retching	1	0
Vomiting	71	0
Vomiting neonatal	2	0
Vomiting projectile	3	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	2	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
Swollen tongue	6	0
Tongue oedema	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>171</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Fatigue	2	0
Malaise	30	0
<i>Death and sudden death</i>		
Death	2	2
Sudden infant death syndrome	4	4
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
PFAPA syndrome	1	0
Pyrexia	135	0
<i>Feelings and sensations NEC</i>		
Feeling abnormal	3	0
Feeling cold	2	0
Feeling hot	48	0
Feeling jittery	1	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	167	0
Foaming at mouth	2	0
Glassy eyes	1	0
Induration	1	0
Irritability	54	0
Local reaction	69	0
Local swelling	155	0
Secretion discharge	1	0
Swelling	40	0
<i>Implant and catheter site reactions</i>		
Implant site warmth	1	0
<i>Inflammations</i>		
Inflammation	35	0
<i>Injection site reactions</i>		
Injection site atrophy	1	0
Injection site bruising	5	0
Injection site discharge	1	0
Injection site discolouration	5	0
Injection site erythema	106	0
Injection site granuloma	1	0
Injection site haemorrhage	1	0
Injection site induration	5	0
Injection site inflammation	21	0
Injection site irritation	2	0
Injection site mass	20	0
Injection site oedema	1	0
Injection site pain	18	0
Injection site pruritus	1	0
Injection site rash	7	0
Injection site reaction	43	0
Injection site swelling	96	0
Injection site urticaria	2	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site vesicles	3	0
Injection site warmth	17	0
<b>Mass conditions NEC</b>		
Mass	3	0
<b>Oedema NEC</b>		
Extensive swelling of vaccinated limb	1	0
Localised oedema	2	0
Oedema	2	0
Oedema peripheral	11	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	1	0
Discomfort	6	0
Pain	18	0
Tenderness	5	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse reaction	1	0
<b>Vaccination site reactions</b>		
Vaccination site swelling	1	0
<b>General disorders SOC TOTAL</b>	<b>1167</b>	<b>6</b>



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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	12	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	2	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Food allergy	1	0
Milk allergy	1	0
<i><b>Anaphylactic responses</b></i>		
Anaphylactic reaction	19	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Immunisation reaction	5	0
<b>Immune system disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Gastroenteritis	1	0
<b><i>Bacterial infections NEC</i></b>		
Arthritis bacterial	1	0
Cellulitis	22	0
Injection site cellulitis	1	0
<b><i>Bordetella infections</i></b>		
Pertussis	5	0
<b><i>Central nervous system and spinal infections</i></b>		
Meningitis	1	0
<b><i>Haemophilus infections</i></b>		
Haemophilus infection	1	1
Meningitis haemophilus	1	0
Pneumonia haemophilus	1	0
<b><i>Herpes viral infections</i></b>		
Eczema herpeticum	1	0
Oral herpes	1	0
<b><i>Infections NEC</i></b>		
Abscess	2	0
Injection site abscess	6	0
Injection site infection	4	0
Localised infection	1	0
Vaccination site abscess	2	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchopneumonia	4	1
Lobar pneumonia	1	0
Pneumonia	1	0
<b><i>Neisseria infections</i></b>		
Meningococcal infection	2	0
Meningococcal sepsis	1	0
<b><i>Parainfluenzae viral infections</i></b>		
Croup infectious	1	0
<b><i>Salmonella infections</i></b>		
Salmonellosis	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	4	0
<b><i>Skin structures and soft tissue infections</i></b>		
Eczema infected	2	0
Rash pustular	1	0
Skin infection	2	0
<b><i>Streptococcal infections</i></b>		
Pneumococcal infection	2	0
Pneumococcal sepsis	2	1
<b><i>Upper respiratory tract infections</i></b>		
Acute tonsillitis	1	0
Epiglottitis	2	0
Nasopharyngitis	2	0
Tracheitis	1	0
Upper respiratory tract infection	1	0
<b><i>Urinary tract infections</i></b>		
Urinary tract infection	2	0
<b><i>Viral infections NEC</i></b>		
Bronchiolitis	1	0

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Infections</b> Infections cont'd		
Kaposi's varicelliform eruption	1	0
Viral infection	3	0
Viral upper respiratory tract infection	1	0
<b>Infections SOC TOTAL</b>	<b>90</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Cerebral injuries NEC</i></b>		
Subdural haemorrhage	2	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
<b><i>Maladministrations</i></b>		
Drug administration error	1	0
Inappropriate schedule of drug administration	1	0
Incorrect dose administered	2	0
Wrong drug administered	5	0
Wrong technique in drug usage process	2	0
<b><i>Medication errors NEC</i></b>		
Medication error	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Wound secretion	1	0
<b><i>Overdoses</i></b>		
Accidental overdose	1	0
Overdose	3	0
<b><i>Peripheral nerve injuries</i></b>		
Injury to brachial plexus due to birth trauma	1	0
<b><i>Skin injuries NEC</i></b>		
Contusion	10	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	5	0
Vaccination failure	7	0
<b>Injuries SOC TOTAL</b>	<b>45</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	6	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF white blood cell count increased	1	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 decreased	1	0
Heart rate increased	3	0
<i><b>Immunology analyses NEC</b></i>		
Tryptase increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature increased	23	0
Respiratory rate decreased	1	0
Weight decreased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count increased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	5	0
<i><b>Renal function analyses</b></i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i><b>Toxicology laboratory analyses</b></i>		
Blood mercury abnormal	1	0
<i><b>Urinalysis NEC</b></i>		
Protein urine present	1	0
<i><b>White blood cell analyses</b></i>		
White blood cell count decreased	1	0
White blood cell count increased	2	0
<b>Investigations SOC TOTAL</b>	<b>52</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	19	0
Hypophagia	4	0
Increased appetite	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Cow's milk intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Failure to thrive	1	0
Feeding disorder	12	0
Feeding disorder neonatal	3	0
Feeding disorder of infancy or early childhood	12	0
Weight gain poor	3	0
<i><b>Sugar intolerance (excl glucose intolerance)</b></i>		
Lactose intolerance	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>57</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Arthropathies NEC</i>		
Polyarthritis	1	0
<i>Joint related signs and symptoms</i>		
Joint range of motion decreased	1	0
Joint swelling	6	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	1	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Floppy infant	6	0
Muscle rigidity	9	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	1	0
Neck pain	1	0
Pain in extremity	15	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Musculoskeletal stiffness	5	0
Weight bearing difficulty	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>53</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Hyperreflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Intraventricular haemorrhage	1	0
<i>Coordination and balance disturbances</i>		
Nystagmus	2	0
<i>Developmental disorders cognitive</i>		
Autism	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	2	0
Lethargy	13	0
Loss of consciousness	10	0
Sedation	1	0
Somnolence	38	0
Syncope	12	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	8	0
Hypokinesia	2	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Encephalitis	1	0
<i>Generalised tonic-clonic seizures</i>		
Grand mal convulsion	4	0
<i>Headaches NEC</i>		
Headache	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	43	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	5	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	1	0
Fontanelle bulging	1	0
Grimacing	1	0
Myoclonus	1	0
Presyncope	4	0
Unresponsive to stimuli	26	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hyporesponsive episode	9	0
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsion	45	0
Epilepsy	2	0
Febrile convulsion	6	0
Infantile spasms	2	0



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<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Myoclonic epilepsy	1	0
Partial seizures	4	0
Seizure cluster	1	0
Status epilepticus	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Dysgeusia	1	0
Restless legs syndrome	1	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	2	1
<b><i>Tremor (excl congenital)</i></b>		
Tremor	4	0
<b>Nervous system disorders SOC TOTAL</b>	<b>264</b>	<b>1</b>

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<b>Pregnancy conditions</b>		
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	3	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	6	0
Breath holding	6	0
Staring	8	0
<b><i>Anxiety symptoms</i></b>		
Agitation	4	0
Agitation neonatal	2	0
Anxiety	1	0
Nervousness	1	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Personality change	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	1	0
<b><i>Decreased physical activity levels</i></b>		
Decreased activity	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	1	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	3	0
Food aversion	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	10	0
Mood altered	5	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	2	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	9	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	5	0
<b><i>Panic attacks and disorders</i></b>		
Panic reaction	1	0
<b><i>Perception disturbances</i></b>		
Hallucination	1	0
<b><i>Personality disorders with anxious behaviour (Cluster C)</i></b>		
Dependent personality disorder	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	2	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	8	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Screaming	63	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>147</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Enuresis	1	0
Micturition urgency	1	0
Urinary incontinence	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	11	0
Apnoeic attack	3	0
Dyspnoea	17	0
Grunting	2	0
Hypopnoea	5	0
Respiratory arrest	12	1
Respiratory distress	2	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	11	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	1
<i><b>Coughing and associated symptoms</b></i>		
Cough	11	0
Productive cough	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	1	0
<i><b>Neonatal hypoxic conditions</b></i>		
Apnoea neonatal	2	0
<i><b>Newborn respiratory disorders NEC</b></i>		
Respiratory disorder neonatal	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Lung disorder	1	1
Respiratory disorder	6	0
<i><b>Tracheal disorders (excl infections and neoplasms)</b></i>		
Tracheal disorder	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking	2	0
Dysphonia	2	0
Increased upper airway secretion	1	0
Rhinorrhoea	3	0
Sneezing	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>102</b>	<b>3</b>

# Case Series Drug Analysis Print

## Name: DTPa IPV HIB

Report Run Date: 20-Feb-2014  
Earliest Reaction Date: 02-Oct-2002

Data Lock Date: 18-Feb-2014 01:01:22  
MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b>Angioedemas</b>		
Angioedema	3	0
Swelling face	10	0
<b>Apocrine and eccrine gland disorders</b>		
Cold sweat	6	0
Hyperhidrosis	6	0
<b>Bullous conditions</b>		
Blister	15	0
Blood blister	2	0
Erythema multiforme	4	0
Pemphigoid	3	0
<b>Dermal and epidermal conditions NEC</b>		
Dry skin	6	0
Macule	1	0
Pain of skin	2	0
Scab	2	0
Skin burning sensation	1	0
Skin discolouration	18	0
Skin discomfort	1	0
Skin disorder	3	0
Skin induration	1	0
Skin lesion	3	0
Skin odour abnormal	1	0
Skin reaction	18	0
Skin sensitisation	1	0
Skin tightness	2	0
Skin warm	9	0
Yellow skin	1	0
<b>Dermatitis and eczema</b>		
Dermatitis allergic	5	0
Dermatitis atopic	1	0
Dermatitis diaper	2	0
Eczema	8	0
Eczema infantile	1	0
Skin irritation	1	0
<b>Erythemas</b>		
Erythema	238	0
Generalised erythema	6	0
Rash erythematous	16	0
<b>Exfoliative conditions</b>		
Skin exfoliation	2	0
<b>Papulosquamous conditions</b>		
Rash papular	5	0
<b>Pigmentation changes NEC</b>		
Post inflammatory pigmentation change	1	0
<b>Pruritus NEC</b>		
Pruritus	9	0
Pruritus generalised	1	0
Rash pruritic	3	0
<b>Purpura and related conditions</b>		
Petechiae	37	0
Purpura	18	0
<b>Rashes, eruptions and exanthems NEC</b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash	81	0
Rash generalised	37	0
Rash macular	48	0
Rash maculo-papular	12	0
Rash vesicular	1	0
<b>Skin dystrophies</b>		
Hypertrophic scar	1	0
<b>Skin haemorrhages</b>		
Skin haemorrhage	1	0
<b>Skin vasculitides</b>		
Vasculitic rash	3	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	7	0
<b>Urticarias</b>		
Urticaria	42	0
Urticaria pigmentosa	1	0
<b>Skin disorders SOC TOTAL</b>	<b>707</b>	<b>0</b>

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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>



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Earliest Reaction Date: 02-Oct-2002

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Obstetric therapeutic procedures</i>		
Vacuum extractor delivery	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Hyperaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	8	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	83	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>108</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>3111</b>	<b>14</b>
<b>TOTAL REPORTS</b>	<b>1265</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>14</b>