

Case Series Drug Analysis Print

Name: FOI 23/943 Serious Reports DTaP/IPV/Hib/HepB Vaccine Analysis Print

Report Run Date: 22-Dec-2023

Data Lock Date: 08-Dec-2023 18:30:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 26.1

FOI 23/943 Serious Reports All serious UK spontaneous suspected Adverse Drug
Reaction (ADR) reports for
DTaP/IPV/Hib/HepB Vaccine Analysis Print: 08/12/2023
DTaP/IPV/Hib/HepB vaccine up to and including

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Reaction Name	Total	Fatal
Blood disorders		
<i>Leukytoses NEC</i>		
Lymphocytic infiltration	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	3	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	8	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac arrest neonatal	1	1
Cardio-respiratory arrest	3	2
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	16	4

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Oral cavity disorders congenital NEC</i>		
Tethered oral tissue	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Ear swelling	3	0
Ear disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye oedema	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	3	0
Gaze palsy	3	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	33	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faecaloma	1	0
Faeces discoloured	11	0
Faeces pale	1	0
Mucous stools	7	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	6	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain upper	11	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	8	0
Gastrooesophageal reflux disease	7	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Infant dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discolouration	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	2	0
Retching	1	0
Vomiting	29	0
Vomiting projectile	16	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	6	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Salivary gland enlargements</i>		
Salivary gland enlargement	1	0
Gastrointestinal disorders SOC TOTAL	169	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	6	0
Decreased activity	1	0
Fatigue	5	0
Malaise	10	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
<i>Death and sudden death</i>		
Death	7	7
Sudden death	4	4
Sudden infant death syndrome	4	4
<i>Febrile disorders</i>		
Pyrexia	110	0
<i>Feelings and sensations NEC</i>		
Chills	4	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	5	0
Thirst decreased	2	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	61	0
Developmental delay	2	0
Developmental regression	1	0
General physical health deterioration	1	0
Glassy eyes	2	0
High-pitched crying	8	0
Illness	1	0
Influenza like illness	1	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	15	0
Screaming	22	0
Secretion discharge	1	0
Swelling	6	0
Swelling face	5	0
<i>Inflamations</i>		
Inflammation	5	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injection site mass	2	0
Injection site pain	1	0
Injection site pruritus	1	0
Injection site swelling	1	0
Injection site vesicles	1	0
<i>Oedema NEC</i>		
Oedema	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Discomfort	6	0
Pain	21	0
Tenderness	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	1	0
Vaccination failure	5	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	2	0
Vaccination site discomfort	1	0
Vaccination site erythema	4	0
Vaccination site haemorrhage	1	0
Vaccination site induration	2	0
Vaccination site inflammation	3	0
Vaccination site mass	5	0
Vaccination site pain	7	0
Vaccination site rash	1	0
Vaccination site swelling	7	0
General disorders SOC TOTAL	379	15

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Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Jaundice cholestatic	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	5	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	4	0
Milk allergy	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	10	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	2	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	31	1

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	8	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
<i>Bordetella infections</i>		
Pertussis	2	0
<i>Central nervous system and spinal infections</i>		
Meningitis	2	0
Meningitis aseptic	2	0
<i>Ear infections</i>		
Ear infection	1	0
<i>Enteroviral infections NEC</i>		
Meningitis enteroviral	1	0
<i>Haemophilus infections</i>		
Haemophilus infection	4	0
Meningitis haemophilus	1	0
<i>Infections NEC</i>		
Abscess	3	0
Infection	2	0
Vaccination site infection	2	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	1	0
Pneumonia	1	0
Pneumonia aspiration	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Skin infection	3	0
<i>Staphylococcal infections</i>		
Staphylococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	1	0
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	2	0
<i>Viral infections NEC</i>		
Bronchiolitis	3	0
Viral rash	1	0
Infections SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Foetal exposure during pregnancy	2	0
Maternal exposure during breast feeding	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	6	0
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	2	0
<i>Non-site specific injuries NEC</i>		
Wound secretion	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Incorrect dose administered	6	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	2	0
<i>Product preparation errors and issues</i>		
Product preparation issue	6	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Skin injuries NEC</i>		
Contusion	7	0
Scratch	1	0
Skin injury	1	0
Injuries SOC TOTAL	41	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac output decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	2	0
Pulse abnormal	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	2	0
<i>Mineral and electrolyte analyses</i>		
Blood magnesium decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	5	0
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	4	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	2	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	3	0
Investigations SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	20	0
Food refusal	2	0
Hypophagia	1	0
Increased appetite	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	4	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
Food aversion	1	0
Poor feeding infant	20	0
Weight gain poor	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Lactic acidosis	1	0
Metabolic acidosis	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	58	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Joint swelling	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	5	0
Muscle tightness	1	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Floppy infant	18	0
Muscle rigidity	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Infantile back arching	4	0
Limb mass	1	0
Musculoskeletal stiffness	5	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Musculoskeletal pain	1	0
Pain in extremity	9	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	57	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	4	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	9	0
Loss of consciousness	3	0
Postictal state	1	0
Somnolence	26	0
Syncope	4	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	8	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	6	0
<i>Headaches NEC</i>		
Headache	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Mental impairment	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	11	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	1	0
Hyporesponsive to stimuli	3	0
Infant irritability	1	0
Myoclonus	1	0
Neurological symptom	1	0
Slow response to stimuli	1	0
Unresponsive to stimuli	27	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hyporesponsive episode	18	0
Muscle spasticity	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	12	0
Infantile spasms	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Seizure	19	0
Status epilepticus	1	0
<i>Sleep disturbances NEC</i>		
Sudden onset of sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
Speech disorder	2	0
<i>Tremor (excl congenital)</i>		
Tremor	3	0
Nervous system disorders SOC TOTAL	185	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Gestational age and weight conditions</i>		
Poor weight gain neonatal	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	7	0
Behaviour disorder	1	0
Breath holding	3	0
Staring	4	0
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	2	0
Nervousness	1	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	1	0
Social avoidant behaviour	2	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	7	0
Middle insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	5	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional distress	4	0
Irritability	30	0
Mood altered	1	0
<i>Increased physical activity levels</i>		
Restlessness	8	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Listless	3	0
<i>Panic attacks and disorders</i>		
Panic reaction	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	2	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	6	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<i>Tic disorders</i>		
Tic	2	0
Psychiatric disorders SOC TOTAL	108	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Anuria	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	2	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	13	0
Dyspnoea	16	0
Hypopnoea	4	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	4	0
Respiratory distress	2	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	3	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	1	0
Respiratory acidosis	1	0
<i>Coughing and associated symptoms</i>		
Cough	12	0
Haemoptysis	1	0
Productive cough	3	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Neonatal hypoxic conditions</i>		
Brief resolved unexplained event	1	0
Infantile apnoea	3	0
Neonatal hypoxia	1	0
<i>Respiratory signs and symptoms NEC</i>		
Use of accessory respiratory muscles	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	1	0
Oropharyngeal pain	1	0
Rhinorrhoea	3	0
Respiratory disorders SOC TOTAL	82	0

Case Series Drug Analysis Print

Name: FOI 23/943 Serious Reports DTaP/IPV/Hib/HepB Vaccine Analysis Print

Report Run Date: 22-Dec-2023
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 08-Dec-2023 18:30:03
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	3	0
<i>Bullous conditions</i>		
Blister	3	0
Dermatitis bullous	1	0
Pemphigoid	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Papule	2	0
Skin burning sensation	1	0
Skin discolouration	9	0
Skin disorder	1	0
Skin induration	2	0
Skin lesion	1	0
Skin plaque	1	0
Skin reaction	2	0
Skin warm	5	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
Dermatitis atopic	1	0
Dermatitis diaper	1	0
Eczema	11	0
Eczema asteatotic	1	0
Eczema infantile	1	0
<i>Dermatitis ascribed to specific agent</i>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	25	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Purpura and related conditions</i>		
Petechiae	8	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	33	0
Rash erythematous	9	0
Rash macular	7	0
Rash papular	1	0
Rash pruritic	2	0
Rash vesicular	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	8	0
Lividity	1	0
<i>Urticarias</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria	11	0
Urticaria chronic	1	0
Urticaria pressure	1	0
Skin disorders SOC TOTAL	174	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	1
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Fibromuscular dysplasia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	12	0
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	4	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	43	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	68	1
TOTAL REACTIONS FOR DRUG	1489	21
TOTAL REPORTS	480	
TOTAL FATAL OUTCOME REPORTS		21