Case Series Drug Analysis Print Name: DTPA HepB HIB IPV Vaccine Drug Analysis Print

Report Run Date:20-Apr-2021Data Lock Date:19-Apr-2021 18:30:04Earliest Reaction Date:27-Jan-2015MedDRA Version:MedDRA 23.1

DTPA HepB HIB IPV Vaccine Drug Analysis Print: All UK, spontaneous suspected Adverse Drug Reaction reports associated with the DTPA HepB HIB IPV vaccine until 19.04.2021.

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Reaction Name	Total	Fatal
Blood disorders		
Leukocytoses NEC		
Lymphocytic infiltration	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	2	0
Marrow depression and hypoplastic anaemias		
Myelosuppression	1	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Blood disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Cardiac disorders		
Rate and rhythm disorders NEC		
Bradycardia	2	0
Tachycardia	7	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	1
Cardiac arrest neonatal	1	1
Cardio-respiratory arrest	2	1
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	14	3

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Earliest Reaction Date: 27-Jan-2015	Weadka version. Weadka 23.1		
Reaction Name		Total	Fatal
Ear disorders			
Ear disorders NEC			
Ear swelling		4	0
Ear disorders SOC TOTAL		4	0

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Reaction Name	Total	Fatal
Eye disorders		
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	1	0
Ocular bleeding and vascular disorders NEC		
Eye haemorrhage	1	0
Ocular disorders NEC		
Dark circles under eyes	1	0
Eye oedema	1	0
Eye swelling	1	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	2	0
Gaze palsy	3	0
Strabismus	1	0
Ocular sensation disorders		
Photophobia	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	1	0
Eve disorders SOC TOTAL	15	0

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Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	40	0
Diarrhoea haemorrhagic	1	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Faecal abnormalities NEC		
Abnormal faeces	4	0
Faecaloma	1	0
Faeces discoloured	11	0
Faeces hard	1	0
Faeces pale	1	0
Mucous stools	7	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Flatulence	6	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	11	0
Abdominal pain upper	11	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	9	0
Gastrooesophageal reflux disease	6	0
Gastrointestinal disorders NEC		
Gastrointestinal disorder	2	0
Gastrointestinal dyskinetic disorders		
Infant dyschezia	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1	0
Gastrointestinal spastic and hypermotility disorders		
Frequent bowel movements	2	0
Gingival disorders, signs and symptoms NEC		
Gingival discolouration	1	0
Nausea and vomiting symptoms		
Retching	1	0
Vomiting	35	0
Vomiting projectile	12	0
Non-site specific gastrointestinal haemorrhages		
Haematochezia	6	0
Oral dryness and saliva altered		
Salivary hypersecretion	1	0
Oral soft tissue swelling and oedema		
Lip swelling	2	0
Salivary gland enlargements		
Salivary gland enlargement	1	0
Tongue signs and symptoms		
Protrusion tongue	1	0
Gastrointestinal disorders SOC TOTAL	178	0

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Reaction Name	Total	Fatal
General disorders		
Asthenic conditions		-
Asthenia	6	0
Decreased activity	1	0
Fatigue	4	0
Malaise	11	0
Body temperature altered		-
Hyperthermia	1	0
Death and sudden death		
Death	4	4
Sudden death	3	3
Sudden infant death syndrome	4	4
Febrile disorders		
Pyrexia	112	0
Feelings and sensations NEC		
Chills	6	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	4	0
Thirst decreased	2	0
Gait disturbances		
Gait disturbance	3	0
Gait inability	1	0
General signs and symptoms NEC		
Condition aggravated	2	0
Crying	65	0
Developmental delay	1	0
Developmental regression	1	0
General physical health deterioration	1	0
Glassy eyes	3	0
High-pitched crying	6	0
Induration	2	0
Influenza like illness	1	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	14	0
Screaming	22	0
Secretion discharge	1	0
Swelling	5	0
Swelling face	4	0
Inflammations		
Inflammation	3	0
Systemic inflammatory response syndrome	1	0
Injection site reactions		
Injection site discolouration	1	0
Injection site induration	1	0
Injection site mass	2	0
Injection site reaction	1	0
Injection site vesicles	1	0
Oedema NEC		
Oedema	1	0
Oedema peripheral	1	0
Pain and discomfort NEC		
Discomfort	5	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		i atai
Pain	25	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site erythema	11	0
Vaccination site haemorrhage	1	0
Vaccination site induration	2	0
Vaccination site inflammation	3	0
Vaccination site mass	9	0
Vaccination site pain	6	0
Vaccination site rash	1	0
Vaccination site swelling	8	0
Vaccination site vesicles	1	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	383	11

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 Total	Fatal
1	0
1	0
2	0
	Total 1 1 2

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Immune system disordersAllergic conditions NEC9Hypersensitivity9Multiple allergies1Allergies to foods, food additives, drugs and other chemicals1Allergy to vaccine1Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses1Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1Immunodeficiency1	Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 23.1		
Allergic conditions NEC9Hypersensitivity9Multiple allergies1Allergies to foods, food additives, drugs and other chemicals1Allergy to vaccine1Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1Immunodeficiency1	Reaction Name	<u>Total</u>	Fatal
Hypersensitivity9Multiple allergies1Allergies to foods, food additives, drugs and other chemicals1Allergy to vaccine1Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Immune system disorders		
Multiple allergies1Allergies to foods, food additives, drugs and other chemicals1Allergy to vaccine1Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Allergic conditions NEC		
Allergies to foods, food additives, drugs and other chemicals1Allergy to vaccine1Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Hypersensitivity	9	0
Allergy to vaccine1Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses3Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Multiple allergies	1	0
Food allergy4Milk allergy3Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Allergies to foods, food additives, drugs and other chemicals		
Milk allergy3Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Allergy to vaccine	1	0
Anaphylactic and anaphylactoid responses8Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Food allergy	4	0
Anaphylactic reaction8Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Milk allergy	3	0
Anaphylactic shock1Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Anaphylactic and anaphylactoid responses		
Atopic disorders1Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Anaphylactic reaction	8	0
Atopy1Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Anaphylactic shock	1	0
Seasonal allergy1Immune and associated conditions NEC1Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Atopic disorders		
Immune and associated conditions NECHaemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Atopy	1	0
Haemophagocytic lymphohistiocytosis1Immune system disorder1Immunodeficiency disorders NEC1Immunodeficiency1	Seasonal allergy	1	0
Immune system disorder 1 Immunodeficiency disorders NEC 1 Immunodeficiency 1	Immune and associated conditions NEC		
Immunodeficiency disorders NEC 1 Immunodeficiency 1	Haemophagocytic lymphohistiocytosis	1	1
Immunodeficiency 1	Immune system disorder	1	0
Immunodeficiency 1	Immunodeficiency disorders NEC		
Immune system disorders COC TOTAL		1	0
Immune system disorders SOC TOTAL 132	Immune system disorders SOC TOTAL	32	1

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Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Cellulitis	2	0
Meningitis bacterial	1	
Skin bacterial infection	1	
Vaccination site cellulitis	1	
Bordetella infections		
Pertussis	2	0
Central nervous system and spinal infections		
Meningitis	2	0
Meningitis aseptic	2	0
Ear infections		
Ear infection	1	0
Enteroviral infections NEC		
Meningitis enteroviral	1	0
Haemophilus infections		
Haemophilus infection	4	0
Meningitis haemophilus	1	0
Infections NEC		
Abscess	3	0
Abscess limb	1	0
Infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	2	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Pneumonia	1	0
Skin structures and soft tissue infections		
Eczema infected	1	0
Skin infection	1	0
Staphylococcal infections		
Staphylococcal infection	1	0
Upper respiratory tract infections		
Croup infectious	1	0
Nasopharyngitis	1	0
Urinary tract infections		
Urinary tract infection	2	0
Viral infections NEC		
Bronchiolitis	2	0
Viral rash	1	0
Infections SOC TOTAL	38	0

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Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during breast feeding	1	0
Medication errors, product use errors and issues NEC		
Wrong technique in product usage process	1	0
Muscle, tendon and ligament injuries		
Muscle injury	1	0
Non-site specific injuries NEC		
Wound secretion	1	0
Product administration errors and issues		
Accidental overdose	1	C
Inappropriate schedule of product administration	1	C
Incorrect dose administered	5	C
Product administered at inappropriate site	1	C
Product administered to patient of inappropriate age	1	C
Product preparation errors and issues		
Product preparation issue	5	C
Product prescribing errors and issues		
Product prescribing error	1	C
Product storage errors and issues in the product use system		
Product storage error	1	C
Skin injuries NEC		
Contusion	5	C
Scratch	1	0
Skin injury	1	0
Vaccination related complications		
Vaccination failure	5	C
Injuries SOC TOTAL	32	0

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Reaction Name	Total	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	2	0
Heart rate and pulse investigations		
Heart rate decreased	1	0
Heart rate increased	1	0
Pulse abnormal	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	2	0
Liver function analyses		
Alanine aminotransferase increased	1	0
Mineral and electrolyte analyses		
Blood magnesium decreased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	8	0
Breath sounds abnormal	1	0
Respiratory rate increased	3	0
Protein analyses NEC		
C-reactive protein increased	2	0
Red blood cell analyses		
Haemoglobin decreased	1	0
Urinary tract function analyses NEC		
Urine output decreased	3	0
White blood cell analyses		
Lymphocyte count increased	1	0
Investigations SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	1	0
Decreased appetite	24	0
Food refusal	2	0
Hypophagia	1	0
Fluid intake decreased		
Fluid intake reduced	4	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Food intolerance	2	0
General nutritional disorders NEC		
Feeding disorder	1	0
Food aversion	1	0
Poor feeding infant	20	0
Weight gain poor	1	0
Metabolic acidoses (excl diabetic acidoses)		
Lactic acidosis	1	0
Metabolic acidosis	1	0
Total fluid volume decreased		
Dehydration	1	0
Metabolic disorders SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle related signs and symptoms NEC		
Muscle spasms	2	0
Muscle twitching	3	0
Muscle tone abnormalities		
Floppy infant	15	0
Muscle rigidity	2	0
Muscle weakness conditions		
Muscular weakness	2	0
Musculoskeletal and connective tissue conditions NEC		
Infantile back arching	4	0
Limb mass	1	0
Musculoskeletal stiffness	4	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
Musculoskeletal and connective tissue pain and discomfort		
Musculoskeletal pain	1	0
Pain in extremity	5	0
Soft tissue disorders NEC		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	43	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	4	4 0
Coordination and balance disturbances		
Balance disorder	2	
Nystagmus		0
Cortical dysfunction NEC		
Aphasia		1 0
Disturbances in consciousness NEC		
Depressed level of consciousness		
Lethargy		
Loss of consciousness		
Postictal state		
Somnolence	25	
Syncope	2	2 0
Dyskinesias and movement disorders NEC		
Dyskinesia	8	
Movement disorder		
Psychomotor hyperactivity		0
Eye movement disorders		
VIth nerve paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	Ę	5 0
Headaches NEC		
Headache	1	1 0
Intellectual disabilities		
Intellectual disability	1	1 0
Mental impairment (excl dementia and memo	ry loss)	
Cognitive disorder	1	1 0
Mental impairment	1	1 0
Muscle tone abnormal		
Hypotonia	10	0 0
Narcolepsy and hypersomnia		
Hypersomnia	1	1 0
Nervous system disorders NEC		
Nervous system disorder	1	0 0
Neurological signs and symptoms NEC		
Hyporesponsive to stimuli	3	
Infant irritability	1	0
Myoclonus	1	0
Unresponsive to stimuli	25	5 0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	16	
Muscle spasticity	1	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	1 C
Seizures and seizure disorders NEC		
Epilepsy	1	1 C
Epileptic encephalopathy	1	1 C
Febrile convulsion	9	
Infantile spasms	2	-
Seizure	14	4 C
Status epilepticus	1	1 C
Sleep disturbances NEC		

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<u>Total</u>	Fatal
5	0
1	0
1	0
2	0
3	0
165	0
	5 1 1 2 3

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Reaction Name		Total	Fatal
Pregnancy conditions			
Gestational age and weight conditions			
Poor weight gain neonatal		1	0
Pregnancy conditions SOC TOTAL		1	o

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Reaction Name	Total	Fatal
Product quality issues NEC		
Product quality issue	5	0
null SOC TOTAL	5	0

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Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	8	0
Behaviour disorder	1	0
Breath holding	3	0
Staring	4	0
Affect alterations NEC		
Flat affect	1	0
Anxiety symptoms		
Agitation	4	0
Anxiety	1	0
Nervousness	1	0
Behaviour and socialisation disturbances		
Personality change	1	0
Social avoidant behaviour	1	0
Cognitive and attention disorders and disturbances NEC		
Daydreaming	1	0
Communications disorders		
Mutism	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	7	0
Middle insomnia	1	0
Emotional and mood disturbances NEC		
Anger	2	0
Emotional distress	3	0
Irritability	37	0
Mood altered	1	0
Increased physical activity levels		-
Restlessness	12	0
Mood alterations with depressive symptoms		-
Decreased interest	1	0
Depressed mood	1	0
Mood disorders NEC		-
Listless	2	0
Parasomnias		0
Sleep terror	1	0
Pervasive developmental disorders NEC	0	0
Autism spectrum disorder	2	0
Psychiatric symptoms NEC	1	0
Decreased eye contact <i>Sleep disorders NEC</i>	1	0
	5	0
Sleep disorder	C	0
Speech articulation and rhythm disturbances	4	0
Dysphemia Suisidal and solf injurious behaviour	1	0
Suicidal and self-injurious behaviour	4	0
Intentional self-injury	1	0
Psychiatric disorders SOC TOTAL	105	0

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Reaction Name		Total	Fatal
Renal & urinary disorders			
Renal failure and impairment			
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		
Testicular and epididymal disorders NEC		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		-
Apnoea	12	C
Dyspnoea	11	C
Hypopnoea	3	C
Irregular breathing	1	C
Respiration abnormal	3	C
Respiratory arrest	3	C
Respiratory distress	1	C
Bronchospasm and obstruction		
Wheezing	3	C
Conditions associated with abnormal gas exchange		
Cyanosis central	1	C
Respiratory acidosis	1	C
Coughing and associated symptoms		
Cough	10	C
Haemoptysis	1	C
Productive cough	3	C
Sputum discoloured	1	0
Laryngeal spasm, oedema and obstruction		
Stridor	1	0
Lower respiratory tract inflammatory and immunologic conditions		
Pneumonia aspiration	1	0
Lower respiratory tract signs and symptoms		
Hiccups	1	C
Nasal disorders NEC		
Epistaxis	2	C
Neonatal hypoxic conditions		
Infantile apnoea	3	0
Neonatal hypoxia	1	0
Respiratory signs and symptoms NEC		
Use of accessory respiratory muscles	1	C
Upper respiratory tract signs and symptoms		
Choking	1	C
Dysphonia	1	0
Oropharyngeal pain	2	C
Rhinorrhoea	4	0
Respiratory disorders SOC TOTAL	72	0

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	3 0
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Reaction Name	Total	Fatal
Vascular disorders		
Arterial infections and inflammations		
Kawasaki's disease	1	1
Circulatory collapse and shock		
Circulatory collapse	2	0
Haemorrhages NEC		
Haemorrhage	1	0
Non-site specific necrosis and vascular insufficiency NEC		
Fibromuscular dysplasia	1	0
Peripheral vascular disorders NEC		
Cyanosis	9	0
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	3	0
Poor peripheral circulation	1	0
Site specific vascular disorders NEC		
Pallor	36	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular disorders SOC TOTAL	56	
TOTAL REACTIONS FOR DRUG	1471	16
TOTAL REPORTS	500	
TOTAL FATAL OUTCOME REPORTS		16