

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Data Lock Date: 03-Mar-2023 18:30:05  
Earliest Reaction Date: 27-Sep-2017  
MedDRA Version: MedDRA 25.1

FOI 23/135 DTPA All UK spontaneous suspected Adverse Drug Reaction  
HepB HIB IPV (6-in-1) (ADR) reports associated with the 6-in-1 vaccine from  
Vaccine Analysis Print 01/01/2020 up to and including 03/03/2023  
(VAP):

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	2	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
<b>Blood disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	4	0
<b>Cardiac disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Ear swelling	1	0
<b>Ear disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Ocular discomfort	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	3	0
Strabismus	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	20	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	2	0
Faeces hard	1	0
Mucous stools	4	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	3	0
Abdominal pain upper	8	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	8	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Infant dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Retching	1	0
Vomiting	22	0
Vomiting projectile	7	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	3	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>96</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	3	0
Decreased activity	1	0
Fatigue	4	0
Malaise	3	0
<i><b>Death and sudden death</b></i>		
Sudden death	2	2
Sudden infant death syndrome	1	1
<i><b>Febrile disorders</b></i>		
Pyrexia	56	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	3	0
Feeling abnormal	1	0
Feeling hot	2	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	1	0
Crying	22	0
Developmental delay	1	0
High-pitched crying	7	0
Illness	4	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	9	0
Screaming	4	0
Swelling	7	0
Swelling face	1	0
<i><b>Inflammations</b></i>		
Inflammation	10	0
Systemic inflammatory response syndrome	1	0
<i><b>Injection site reactions</b></i>		
Injection site mass	2	0
Injection site pain	1	0
Injection site pruritus	1	0
Injection site swelling	2	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	1	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	1	0
Discomfort	1	0
Pain	7	0
Tenderness	2	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	4	0
Drug ineffective	1	0
<i><b>Vaccination site reactions</b></i>		
Extensive swelling of vaccinated limb	3	0
Vaccination site discomfort	1	0
Vaccination site erythema	4	0
Vaccination site haemorrhage	1	0
Vaccination site inflammation	3	0
Vaccination site mass	4	0
Vaccination site pain	3	0



## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site pruritus	1	0
Vaccination site rash	3	0
Vaccination site swelling	4	0
Vaccination site vesicles	1	0
Vaccination site warmth	2	0
<b>General disorders SOC TOTAL</b>	<b>198</b>	<b>3</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Food allergy	2	0
Milk allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<i>Atopic disorders</i>		
Atopy	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Haemophagocytic lymphohistiocytosis	1	1
<b>Immune system disorders SOC TOTAL</b>	<b>14</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	5	0
<i><b>Central nervous system and spinal infections</b></i>		
Meningitis	1	0
<i><b>Infections NEC</b></i>		
Abscess limb	1	0
Vaccination site abscess	1	0
Vaccination site infection	2	0
<i><b>Influenza viral infections</b></i>		
Influenza	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Skin infection	2	0
<i><b>Staphylococcal infections</b></i>		
Staphylococcal infection	1	0
<i><b>Upper respiratory tract infections</b></i>		
Tonsillitis	1	0
<i><b>Viral infections NEC</b></i>		
Bronchiolitis	2	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>20</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	6	0
Wrong technique in product usage process	1	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle injury	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></i>		
Inappropriate schedule of product administration	1	0
Incorrect dose administered	6	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	2	0
<i><b>Product preparation errors and issues</b></i>		
Product preparation issue	6	0
<i><b>Product storage errors and issues in the product use system</b></i>		
Product storage error	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	3	0
Scratch	1	0
<b>Injuries SOC TOTAL</b>	<b>33</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	4	0
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	2	0
<b>Investigations SOC TOTAL</b>	<b>11</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	11	0
Hypophagia	1	0
Increased appetite	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
Poor feeding infant	3	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Lactic acidosis	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Joint swelling	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	3	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	6	0
Muscle rigidity	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Infantile back arching	2	0
Limb mass	1	0
Musculoskeletal stiffness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Flank pain	1	0
Musculoskeletal pain	1	0
Pain in extremity	7	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>29</b>	<b>0</b>



## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	2	0
<i><b>Disturbances in consciousness NEC</b></i>		
Depressed level of consciousness	1	0
Lethargy	2	0
Loss of consciousness	2	0
Postictal state	1	0
Somnolence	9	0
Syncope	4	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Dyskinesia	3	0
Movement disorder	1	0
<i><b>Eye movement disorders</b></i>		
VIth nerve paralysis	1	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	4	0
<i><b>Headaches NEC</b></i>		
Headache	2	0
<i><b>Intellectual disabilities</b></i>		
Intellectual disability	1	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Mental impairment	1	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	2	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	1	0
Myoclonus	1	0
Unresponsive to stimuli	8	0
<i><b>Neuromuscular disorders NEC</b></i>		
Hypotonic-hypo-responsive episode	4	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Epilepsy	1	0
Epileptic encephalopathy	1	0
Febrile convulsion	4	0
Infantile spasms	1	0
Seizure	8	0
Status epilepticus	1	0
<i><b>Sleep disturbances NEC</b></i>		
Sudden onset of sleep	1	0
<i><b>Speech and language abnormalities</b></i>		
Dysarthria	1	0
Speech disorder	1	0
<i><b>Tremor (excl congenital)</b></i>		
Tremor	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>70</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	3	0
<b>null SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Abnormal behaviour NEC</i>		
Staring	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	1	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	3	0
Irritability	11	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Phonophobia	1	0
<i>Increased physical activity levels</i>		
Restlessness	6	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic reaction	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Tic disorders</i>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>43</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	3	0
Hypopnoea	1	0
Irregular breathing	1	0
Respiration abnormal	2	0
Respiratory arrest	2	0
Respiratory distress	1	0
Tachypnoea	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	6	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	1	0
<i><b>Neonatal hypoxic conditions</b></i>		
Brief resolved unexplained event	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Use of accessory respiratory muscles	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>22</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	1	0
Hyperhidrosis	1	0
<i><b>Bullous conditions</b></i>		
Blister	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	2	0
Papule	2	0
Skin discolouration	4	0
Skin disorder	1	0
Skin reaction	1	0
Skin warm	3	0
Skin weeping	1	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	1	0
Dermatitis allergic	2	0
Dermatitis atopic	3	0
Eczema	8	0
Eczema infantile	1	0
<i><b>Erythemas</b></i>		
Erythema	13	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	5	0
<i><b>Purpura and related conditions</b></i>		
Petechiae	5	0
Purpura	1	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	30	0
Rash erythematous	7	0
Rash macular	10	0
Rash papular	6	0
Rash pruritic	2	0
Rash vesicular	1	0
<i><b>Skin and subcutaneous conditions NEC</b></i>		
Skin mass	1	0
<i><b>Skin and subcutaneous tissue ulcerations</b></i>		
Skin erosion	1	0
<i><b>Skin vasomotor conditions</b></i>		
Livedo reticularis	6	0
<i><b>Urticarias</b></i>		
Urticaria	8	0
<b>Skin disorders SOC TOTAL</b>	<b>129</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 27-Sep-2017

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Therapeutic procedures NEC</i>		
Injection	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/135 DTPA HepB HIB IPV (6-in-1) Vaccine Analysis Print (VAP)

Report Run Date: 06-Mar-2023  
 Earliest Reaction Date: 27-Sep-2017

Data Lock Date: 03-Mar-2023 18:30:05  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<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	4	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	17	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>736</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>284</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>