Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 27-Jan-2015 MedDRA 25.1 MedDRA Version:

Infanrix Hexa Vaccine All UK spontaneous ADR reports for Infanrix Hexa Analysis Print: All UK spontaneous ADR reports for Infanrix Hexa Since the start of the Yellow Card system to

11/11/2022

## Name: Infanrix Hexa Vaccine Analysis Print

Report Run Date: 23-Nov-2022 Data Lock Date: 16-Nov-2022 18:30:05 Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Blood disorders		
Leukocytoses NEC		
Lymphocytic infiltration	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	3	3 0
Marrow depression and hypoplastic anaemias		
Myelosuppression	1	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenia	2	2 0
Blood disorders SOC TOTAL	8	sl o

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Reaction Name	Total	Fatal
Cardiac disorders		
Rate and rhythm disorders NEC		
Bradycardia	2	0
Tachycardia	8	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	15	3

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Reaction Name	Total	Fatal
Congenital disorders		
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	1	l o

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	1	0
Ear swelling	4	0
Ear disorders SOC TOTAL	5	l o

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Reaction Name	Total	Fatal
Eye disorders		
Cataract conditions		
Cataract	1	0
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 discomfort	1	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	3	0
Gaze palsy	3	0
Strabismus	1	0
Ocular sensation disorders		
Photophobia	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	1	0
Visual disorders NEC		
Vision blurred	1	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	1	0
Eve disorders SOC TOTAL	20	0

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	48	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	8	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Flatulence	7	0
Gastrointestinal and abdominal pains (excl oral and throat)	Í	Ŭ
Abdominal pain	11	0
Abdominal pain upper	14	
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	12	0
Gastrooesophageal reflux disease	7	0
Gastrointestinal disorders NEC	,	J
Gastric disorder	1	0
Gastro disorder  Gastrointestinal disorder	2	0
Gastrointestinal disorders		U
Infant dyschezia	1	0
Gastrointestinal signs and symptoms NEC		U
Abdominal discomfort	3	0
Gastrointestinal spastic and hypermotility disorders	3	U
Frequent bowel movements	2	0
		U
Gingival disorders, signs and symptoms NEC Gingival discolouration	1	0
	I	0
Nausea and vomiting symptoms	2	0
Nausea	2	0
Retching	1	0
Vomiting	45	
Vomiting projectile	16	0
Non-site specific gastrointestinal haemorrhages	_	0
Haematochezia	6	0
Oral dryness and saliva altered	4	_
Salivary hypersecretion	7	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	214	0

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Earliest Reaction Date: 27-Jan-2015	MedDRA Version: MedDRA 25.1	
Reaction Name	Total	<u>Fatal</u>
General disorders		
Asthenic conditions		
Asthenia	7	0
Decreased activity		0
Fatigue	6	
Malaise	12	. 0
Body temperature altered		
Hyperthermia		0
Death and sudden death		
Death	4	4
Sudden death	4	4
Sudden infant death syndrome	4	4
Febrile disorders		
Pyrexia	133	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	3	0
Crying	69	0
Developmental delay	2	. 0
Developmental regression	1	0
General physical health deterioration	1	0
Glassy eyes	3	0
High-pitched crying	g	0
Illness	3	0
Induration	1	0
Influenza like illness	1	0
Moaning	2	. 0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	18	0
Screaming	23	0
Secretion discharge	1	0
Swelling	8	0
Swelling face	4	. 0
Inflammations		
Inflammation	g	0
Systemic inflammatory response syndrom	e 1	0
Injection site reactions		
Injection site induration	1	0
Injection site mass	2	. 0
Injection site pain		0
Injection site pruritus	1	0
Injection site swelling	2	0
Injection site vesicles	1	0
Oedema NEC		
Oedema	1	0
Oedema peripheral	1	0

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Lamest Reaction Date. 21-Jan-2013	WedDRA Version, WedDRA 25.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
General disorders General disorders cont'd			
Pain and discomfort NEC			
Axillary pain		1	0
Discomfort		6	0
Pain		25	0
Tenderness		2	0
Therapeutic and nontherapeutic responses			
Adverse drug reaction		4	0
Drug ineffective		1	0
Vaccination failure		5	0
Vaccination site reactions			
Extensive swelling of vaccinated limb		2	0
Vaccination site discomfort		1	0
Vaccination site erythema		12	0
Vaccination site haemorrhage		1	0
Vaccination site induration		2	0
Vaccination site inflammation		5	0
Vaccination site mass		11	0
Vaccination site pain		7	0
Vaccination site rash		4	0
Vaccination site swelling		9	0
Vaccination site vesicles		1	0
Vaccination site warmth		2	0
General disorders SOC TOTAL		461	12

## Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	1	0
Jaundice cholestatic	1	0
Hepatocellular damage and hepatitis NEC		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	3	0

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergy to metals	1	0
Hypersensitivity	9	0
Multiple allergies	1	0
Allergies to foods, food additives, drugs and other chemicals		
Allergy to vaccine	1	0
Food allergy	4	0
Milk allergy	3	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	10	0
Anaphylactic shock	1	0
Atopic disorders		
Atopy	1	0
Seasonal allergy	1	0
Immune and associated conditions NEC		
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	35	1

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Infections		
Bacterial infections NEC		
Cellulitis	7	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
Bordetella infections		
Pertussis	2	0
Central nervous system and spinal infections		
Meningitis	2 2	0
Meningitis aseptic	2	0
Ear infections		
Ear infection	1	0
Enteroviral infections NEC		
Meningitis enteroviral	1	0
Haemophilus infections		
Haemophilus infection	4	1
Meningitis haemophilus	1	0
Infections NEC		
Abscess	3	0
Abscess limb	2	
Infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	2	0
Lower respiratory tract and lung infections		_
Bronchitis	1	0
Lower respiratory tract infection	1	0
Pneumonia	1	0
Pneumonia aspiration	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		_
Sepsis	1	0
Skin structures and soft tissue infections  Eczema infected		_
	1	0
Skin infection	3	0
Staphylococcal infections	1	0
Staphylococcal infection	1	U
Upper respiratory tract infections  Croup infectious	1	0
Nasopharyngitis	1	0
Urinary tract infections	'	U
Urinary tract infection	2	0
Viral infections NEC		U
Bronchiolitis	3	0
Viral rash	1	0
Infections SOC TOTAL	50	
IIIIIECUOTIS GOO TOTAL	<u> </u>	U

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	1	0
Medication errors, product use errors and issues NEC		
Medication error	4	0
Wrong technique in product usage process	2	0
Muscle, tendon and ligament injuries		
Muscle injury	2	0
Non-site specific injuries NEC		
Wound secretion	1	0
Overdoses NEC		
Overdose	1	0
Product administration errors and issues		
Accidental overdose	1	0
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	3	0
Product preparation errors and issues		
Product preparation issue	6	0
Product prescribing errors and issues		
Product prescribing error	1	0
Product storage errors and issues in the product use system		
Product storage error	1	0
Skin injuries NEC		
Contusion	7	0
Scratch	1	0
Skin injury	1	0
Injuries SOC TOTAL	41	0

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
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
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	2	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	9	0
Breath sounds abnormal	1	0
Respiratory rate decreased	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	33	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	1	0
Decreased appetite	26	0
Food refusal	2	0
Hypophagia	2	0
Increased appetite	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	65	0

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Muscle & tissue disorders		
Joint related disorders NEC		
Periarthritis	1	0
Joint related signs and symptoms		
Joint swelling	1	0
Muscle related signs and symptoms NEC		
Muscle spasms	4	0
Muscle twitching	3	0
Muscle tone abnormalities		
Floppy infant	17	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		
Flank pain	1	0
Musculoskeletal pain	1	0
Pain in extremity	10	0
Soft tissue disorders NEC		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	55	0

	DRA Version: MedDRA 25.1	
Reaction Name	Total	<u> Fatal</u>
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	4	4 0
Coordination and balance disturbances		
Balance disorder	2	2 0
Nystagmus	1	1 0
Cortical dysfunction NEC		
Aphasia	1	1 0
Disturbances in consciousness NEC		
Depressed level of consciousness	1	1 0
Lethargy	3	3 0
Loss of consciousness	2	2 0
Postictal state	1	1 0
Somnolence	27	7 0
Syncope	4	1 0
Dyskinesias and movement disorders NEC		
Dyskinesia	8	3 0
Movement disorder	1	1 0
Psychomotor hyperactivity	1	1 0
Eye movement disorders		
VIth nerve paralysis	1	1 0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	6	6 0
Headaches NEC		
Headache	2	2 0
Intellectual disabilities		
Intellectual disability	1	1 0
Mental impairment (excl dementia and memory l	oss)	
Cognitive disorder	1	1 0
Mental impairment	1	1 0
Muscle tone abnormal		
Hypotonia	10	
Narcolepsy and hypersomnia		
Hypersomnia	1	1 0
Nervous system disorders NEC		
Nervous system disorder	1	1 0
Neurological signs and symptoms NEC		
Dizziness	1	1 0
Hyporesponsive to stimuli	3	3 0
Infant irritability	1	1 0
Myoclonus	1	1 0
Unresponsive to stimuli	27	7 0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	17	7 0
Muscle spasticity	1	1 0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	1 0
Seizures and seizure disorders NEC		
Epilepsy	2	2 0
Epileptic encephalopathy		
Febrile convulsion	11	_
Infantile spasms		1
Seizure	19	
Status epilepticus		أ ا

## Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	Total	Fatal
Nervous system disorders disorders cont'd		
Sleep disturbances NEC		
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	1	0
Speech disorder	2	0
Tremor (excl congenital)		
Tremor	3	0
Nervous system disorders SOC TOTAL	181	0

#### Name: Infanrix Hexa Vaccine Analysis Print

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

### Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	<u>Total</u>	Fatal
Product quality issues NEC		
Product quality issue	5	o
null SOC TOTAL	5	il ol

Psychiatric disorders	Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Abnormal behaviour NEC           Abnormal behaviour disorder         1           Behaviour disorder         1           Breath holding         3           Staring         4           Affect alterations NEC         1           Flat affect         1           Anxiety disorders NEC         2           Separation anxiety disorder         1           Anxiety symptoms         3           Agitation         5           Anxiety symptoms         3           Nervousness         1           Personality change         2           Social avoidant behaviour         2           Personality change         1           Social avoidant behaviour         2           Cognitive and attention disorders and disturbances NEC           Daydreaming         1           Communications disorders         1           Communications disorders         1           Communication disorders         1           Distuntation disorders         1	Reaction Name	<u> Total</u>	<u>Fatal</u>
Abnormal behaviour   Behaviour disorder   1	Psychiatric disorders		
Behaviour disorder   1			
Breath holding   Staring   Staring   A	Abnormal behaviour	8	0
Staring   Affect alterations NEC   Flat affect   1   0   0	Behaviour disorder	1	0
Affect alterations NEC Flat affect Flat affect Flat affect Flat affect Anxiety disorders NEC Separation anxiety disorder Anxiety symptoms Agitation Anxiety Nervousness Behaviour and socialisation disturbances Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Communications disorders Autism Disturbances in initiating and maintaining sleep Insomnia Middle insomnia Dyssomnias Poor quality sleep Emotional distress Irritability Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Mood alterations with depressive symptoms Decreased physical Depressed mood Mood disorders NEC Listless 10 Panic reaction Parasomnias Sleep error Parasomias Sleep terror Parasive developmental disorders NEC Autism spectrum disorder Sleep disorder NEC Sleep disorders NEC Sleep disorders NEC Sleep disorders NEC Sleep disorders NEC Sleep disorder T 0 Speech articulation and rhythm disturbances Dysphemia 1 0 Speech articulation and rhythm disturbances Dysphemia	Breath holding	3	0
Flat affect		4	0
Anxiety disorders NEC   Separation anxiety disorder   1	Affect alterations NEC		
Separation anxiety disorder	Flat affect	1	0
Anxiety symptoms	Anxiety disorders NEC		
Agitation Anxiety Anxi	Separation anxiety disorder	1	0
Anxiety Nervousness Behaviour and socialisation disturbances Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Communications disorders Communications disorders Communication disorder Mutism Disturbances in initiating and maintaining sleep Insomnia Dyssomnias Poor quality sleep Emotional and mood disturbances NEC Anger Emotional distress Irritability Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Nood alterations with depressive symptoms Decreased interest Depressed mood Mood disorders NEC Listless Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Autism spectrum disorder Speech articulation and rhythm disturbances Dysphemia 1 0 Speech articulation and rhythm disturbances	Anxiety symptoms		
Nervousness	Agitation	5	0
Behaviour and socialisation disturbances Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Communications disorders Communication disorder Mutism Insomnia Inritability Insomnia disturbances NEC Inritability Insomnia distress Insomnia inso	Anxiety	2	0
Personality change Social avoidant behaviour  Cognitive and attention disorders and disturbances NEC Daydreaming  Communications disorders  Communication disorder  Mutism Disturbances in initiating and maintaining sleep Insomnia Middle insomnia Dyssomnias Poor quality sleep  Emotional and mood disturbances NEC Anger Emotional distress Irritability Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Mood alterest Depressed mood Mood disorders NEC Listless Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Auger Speech articulation and rhythm disturbances Dysphemia  1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia 1 0  Speech articulation and rhythm disturbances Dysphemia	Nervousness	1	0
Social avoidant behaviour  Cognitive and attention disorders and disturbances NEC  Daydreaming  Communications disorders  Communication disorder  Mutism  Disturbances in initiating and maintaining sleep Insomnia  Middle insomnia  Dyssomnias  Poor quality sleep  Emotional and mood disturbances NEC  Anger  Emotional distress Irritability  Mood altered  Fear symptoms and phobic disorders (incl social phobia) Phonophobia  Increased physical activity levels  Restlessness  Mood alterest Depressed mood  Mood disorders NEC  Listless  Panic reaction  Parasomnias Sleep terror  Parasomnias Sleep terror  Pervasive developmental disorders NEC  Autism spectrum disorder  Psychiatric symptoms NEC Decreased eye contact  Sleep disorder NEC Speech articulation and rhythm disturbances Dysphemia  1 0 0	Behaviour and socialisation disturbances		
Cognitive and attention disorders and disturbances NEC Daydreaming Communications disorders Communication disorder Mutism I	Personality change	1	0
Daydreaming Communications disorders Communications disorder Mutism Disturbances in initiating and maintaining sleep Insomnia Middle insomnia Dyssomnias Poor quality sleep Emotional and mood disturbances NEC Anger Emotional distress Irritability Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Mood alterations with depressive symptoms Decreased interest Depressed mood Mood disorders NEC Listless Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Autism spectrum disorder Psychiatric symptoms NEC Decreased eye contact Sleep disorders NEC Speech articulation and rhythm disturbances Dysphemia  1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Social avoidant behaviour	2	0
Daydreaming Communications disorders Communications disorder Mutism Disturbances in initiating and maintaining sleep Insomnia Middle insomnia Dyssomnias Poor quality sleep Emotional and mood disturbances NEC Anger Emotional distress Irritability Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Mood alterations with depressive symptoms Decreased interest Depressed mood Mood disorders NEC Listless Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Autism spectrum disorder Psychiatric symptoms NEC Decreased eye contact Sleep disorders NEC Speech articulation and rhythm disturbances Dysphemia  1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Cognitive and attention disorders and disturbances NEC		
Communication disorder Mutism Disturbances in initiating and maintaining sleep Insomnia Middle insomnia Poor quality sleep Poor quality sleep Emotional and mood disturbances NEC Anger Emotional distress Irritability Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Mood alterest Decreased interest Depressed mood Mood disorders NEC Listless Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Autism spectrum disorder Psychiatric symptoms NEC Decreased eye contact Sleep disorder NEC Sleep disorder NEC Sleep disorder SEC Speech articulation and rhythm disturbances Dysphemia		1	0
Mutism Disturbances in initiating and maintaining sleep Insomnia 9 0 0 Middle insomnia 1 0 0 Dyssomnias 1 0 0 Dyssomnias 9 0 0 Emotional and mood disturbances NEC	Communications disorders		
Disturbances in initiating and maintaining sleep Insomnia 9 0 Middle insomnia 1 0 Dyssomnias Poor quality sleep 6 0 Emotional and mood disturbances NEC Anger 2 0 Emotional distress 4 0 Irritability 41 0 Mood altered 1 0 Fear symptoms and phobic disorders (incl social phobia) Phonophobia 1 0 Increased physical activity levels Restlessness 13 0 Mood alterations with depressive symptoms Decreased interest 1 0 Depressed mood 1 0 Mood disorders NEC Listless 2 0 Panic attacks and disorders Panic reaction 1 0 Parasomnias Sleep terror 1 0 Pervasive developmental disorders NEC Autism spectrum disorder Psychiatric symptoms NEC Decreased eye contact Sleep disorders NEC Sleep disorder NEC	Communication disorder	1	0
Insomnia   9   0   0   Middle insomnia   1   0   0   0   0   0   0   0   0   0	Mutism	1	0
Insomnia   9   0   0   Middle insomnia   1   0   0   0   0   0   0   0   0   0	Disturbances in initiating and maintaining sleep		
Poor quality sleep  Foor quality sleep  Femotional and mood disturbances NEC  Anger  Emotional distress  Irritability  Mood altered  Fear symptoms and phobic disorders (incl social phobia)  Phonophobia  Increased physical activity levels  Restlessness  Nood alterations with depressive symptoms  Decreased interest  Depressed mood  Mood disorders NEC  Listless  Panic attacks and disorders  Panic reaction  Parasomnias  Sleep terror  Pervasive developmental disorders NEC  Autism spectrum disorder  Psychiatric symptoms NEC  Decreased eye contact  Sleep disorders NEC  Sleep disorder NEC  Sleep disorder SPC  Sleep disorder SPC  Sleep disorder NEC		9	0
Poor quality sleep  Emotional and mood disturbances NEC  Anger Emotional distress 4 0 Irritability Mood altered 4 1 0 Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness 13 0 Mood alterations with depressive symptoms Decreased interest Depressed mood 1 0 Mood disorders NEC Listless Panic attacks and disorders Panic reaction Parasomnias Sleep terror Autism spectrum disorder Pervasive developmental disorders NEC Autism spectrum disorder Pervasive developmental disorders Sleep disorder NEC Sleep disorder NEC Sleep disorder NEC Sleep disorder Speech articulation and rhythm disturbances Dysphemia 1 0	Middle insomnia	1	0
Poor quality sleep  Emotional and mood disturbances NEC  Anger Emotional distress 4 0 Irritability Mood altered 4 1 0 Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness 13 0 Mood alterations with depressive symptoms Decreased interest Depressed mood 1 0 Mood disorders NEC Listless Panic attacks and disorders Panic reaction Parasomnias Sleep terror Autism spectrum disorder Pervasive developmental disorders NEC Autism spectrum disorder Pervasive developmental disorders Sleep disorder NEC Sleep disorder NEC Sleep disorder NEC Sleep disorder Speech articulation and rhythm disturbances Dysphemia 1 0	Dyssomnias		
Emotional and mood disturbances NEC		6	0
Emotional distress			
Emotional distress	Anger	2	0
Mood altered Fear symptoms and phobic disorders (incl social phobia) Phonophobia Increased physical activity levels Restlessness Restlessness 13 0 Mood alterations with depressive symptoms Decreased interest Depressed mood Mood disorders NEC Listless Panic attacks and disorders Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Autism spectrum disorder Pesychiatric symptoms NEC Decreased eye contact Sleep disorders NEC Sleep disorder NEC Sleep disorder Speech articulation and rhythm disturbances Dysphemia 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0		4	0
Mood altered  Fear symptoms and phobic disorders (incl social phobia)  Phonophobia  Increased physical activity levels  Restlessness  Restlessness  13 0  Mood alterations with depressive symptoms  Decreased interest  Depressed mood  Mood disorders NEC  Listless  Panic attacks and disorders  Panic reaction  Parasomnias  Sleep terror  Pervasive developmental disorders NEC  Autism spectrum disorder  Pesychiatric symptoms NEC  Decreased eye contact  Sleep disorders NEC  Sleep disorder NEC  Sleep disorder  Speech articulation and rhythm disturbances  Dysphemia  1 0  1 0  1 0  1 0  1 0  1 0  1 0  1	Irritability	41	0
Phonophobia Increased physical activity levels Restlessness Restlessness Increased interest Decreased interest Depressed mood Increased mood	· ·	1	0
Phonophobia Increased physical activity levels Restlessness Restlessness Increased interest Decreased interest Depressed mood Increased mood	Fear symptoms and phobic disorders (incl social phobia)		
Increased physical activity levels Restlessness 13 0  Mood alterations with depressive symptoms Decreased interest 1 0 Depressed mood 1 0  Mood disorders NEC Listless 2 0  Panic attacks and disorders Panic reaction 1 0  Parasomnias Sleep terror 1 0  Pervasive developmental disorders NEC Autism spectrum disorder 2 0  Psychiatric symptoms NEC Decreased eye contact 1 0  Sleep disorder 1 0  Sleep disorder 7 0  Speech articulation and rhythm disturbances Dysphemia 1 0		1	0
Restlessness 13 0  Mood alterations with depressive symptoms  Decreased interest 1 0 Depressed mood 1 0  Mood disorders NEC  Listless 2 0  Panic attacks and disorders  Panic reaction 1 0  Parasomnias Sleep terror 1 0  Pervasive developmental disorders NEC Autism spectrum disorder 2 0  Psychiatric symptoms NEC Decreased eye contact 1 0  Sleep disorders NEC Sleep disorder 7 0  Speech articulation and rhythm disturbances Dysphemia 1 0	·		
Decreased interest		13	0
Decreased interest	Mood alterations with depressive symptoms		
Mood disorders NEC Listless 2 0 Panic attacks and disorders Panic reaction 1 0 Parasomnias Sleep terror 1 0 Pervasive developmental disorders NEC Autism spectrum disorder 2 0 Psychiatric symptoms NEC Decreased eye contact 1 0 Sleep disorders NEC Sleep disorder 7 0 Speech articulation and rhythm disturbances Dysphemia 1 0		1	0
Listless  Panic attacks and disorders  Panic reaction  Parasomnias  Sleep terror  Pervasive developmental disorders NEC  Autism spectrum disorder  Psychiatric symptoms NEC  Decreased eye contact  Sleep disorders NEC  Sleep disorder  Speech articulation and rhythm disturbances  Dysphemia  2 0  7 0  8 1 0  9 1 0	Depressed mood	1	0
Panic attacks and disorders Panic reaction Parasomnias Sleep terror Pervasive developmental disorders NEC Autism spectrum disorder Autism spectrum disorder Psychiatric symptoms NEC Decreased eye contact Sleep disorders NEC Sleep disorder Speech articulation and rhythm disturbances Dysphemia  1 0	Mood disorders NEC		
Panic reaction  Parasomnias  Sleep terror  1 0  Pervasive developmental disorders NEC  Autism spectrum disorder  Psychiatric symptoms NEC  Decreased eye contact  Sleep disorders NEC  Sleep disorder  Speech articulation and rhythm disturbances  Dysphemia  1 0	Listless	2	0
Parasomnias Sleep terror 1 0 Pervasive developmental disorders NEC Autism spectrum disorder Psychiatric symptoms NEC Decreased eye contact 1 0 Sleep disorders NEC Sleep disorder Speech articulation and rhythm disturbances Dysphemia 1 0	Panic attacks and disorders		
Sleep terror  Pervasive developmental disorders NEC  Autism spectrum disorder  Psychiatric symptoms NEC  Decreased eye contact  Sleep disorders NEC  Sleep disorder  Speech articulation and rhythm disturbances  Dysphemia  1 0	Panic reaction	1	0
Pervasive developmental disorders NEC  Autism spectrum disorder 2 0  Psychiatric symptoms NEC  Decreased eye contact 1 0  Sleep disorders NEC  Sleep disorder 7 0  Speech articulation and rhythm disturbances  Dysphemia 1 0	Parasomnias		
Autism spectrum disorder 2 0  Psychiatric symptoms NEC  Decreased eye contact 1 0  Sleep disorders NEC  Sleep disorder 7 0  Speech articulation and rhythm disturbances  Dysphemia 1 0	Sleep terror	1	0
Autism spectrum disorder 2 0  Psychiatric symptoms NEC  Decreased eye contact 1 0  Sleep disorders NEC  Sleep disorder 7 0  Speech articulation and rhythm disturbances  Dysphemia 1 0	Pervasive developmental disorders NEC		
Psychiatric symptoms NEC  Decreased eye contact  Sleep disorders NEC  Sleep disorder  Speech articulation and rhythm disturbances  Dysphemia  1 0	•	2	0
Decreased eye contact  Sleep disorders NEC  Sleep disorder  Speech articulation and rhythm disturbances  Dysphemia  1 0			
Sleep disorders NEC Sleep disorder 7 0 Speech articulation and rhythm disturbances Dysphemia 1 0	·	1	0
Sleep disorder 7 0  Speech articulation and rhythm disturbances  Dysphemia 1 0	·		
Speech articulation and rhythm disturbances  Dysphemia  1 0	•	7	0
Dysphemia 1 0			
		1	n
Suicidal and self-injurious behaviour			

## Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Intentional self-injury	1	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	129	l 0

## Name: Infanrix Hexa Vaccine Analysis Print

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	2 0

## Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive tract disorders NEC (excl neoplasms)		
Genital blister	1	0
Testicular and epididymal disorders NEC		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	3	0

Dyspnoea	Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1	Total	Fatal
Breathing abnormalities		<u>i otai</u>	ratai
Apnoea			
Dyspnoea Hypopnoea Hypopnoea Hypopnoea Irregular breathing Respiration abnormal Respiratory arrest Respiratory distress Tachypnoea Honchospasm and obstruction Wheezing Conditions associated with abnormal gas exchange Cyanosis central Respiratory acidosis Coughing and associated symptoms Cough Haemoptysis Productive cough Sputum discoloured Laryngeal spasm, oedema and obstruction Stridor Lower respiratory tract signs and symptoms Hiccups Hiscups Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia Respiratory tract signs and symptoms Infantile apnoea Neonatal hypoxia Respiratory tract signs and symptoms Infantile apnoea Neonatal hypoxia Respiratory tract signs and symptoms Infantile apnoea Neonatal hypoxia Respiratory tract signs and symptoms Lobel Great Strate Infantile apnoea Neonatal hypoxia Respiratory tract signs and symptoms Lobel Great Strate Infantile apnoea Neonatal hypoxia Respiratory tract signs and symptoms Choking Dysphonia		4.0	
Hypopnoea   3   1   1   1   1   1   1   1   1   1		1	
Irregular breathing			
Respiration abnormal       3         Respiratory arrest       4         Respiratory distress       2         Tachypnoea       1         Bronchospasm and obstruction       3         Wheezing       3         Conditions associated with abnormal gas exchange       3         Cyanosis central       1         Respiratory acidosis       1         Coughing and associated symptoms       1         Cough and associated symptoms       1         Haemoptysis       1         Productive cough       3         Sputum discoloured       1         Laryngeal spasm, oedema and obstruction       3         Stridor       1         Lower respiratory tract signs and symptoms       1         Hiccups       1         Nasal disorders NEC       2         Epistaxis       2         Neonatal hypoxic conditions       2         Brief resolved unexplained event       1         Infantile apnoea       3         Neonatal hypoxia       1         Respiratory signs and symptoms NEC       1         Use of accessory respiratory muscles       1         Upper respiratory tract signs and symptoms       1		3	
Respiratory arrest Respiratory distress Tachypnoea Tachypnosis central Tachypnosis central Tachypnosis Tachyp		1	0
Respiratory distress		1	0
Tachypnoea  Bronchospasm and obstruction  Wheezing  Conditions associated with abnormal gas exchange  Cyanosis central  Respiratory acidosis  Coughing and associated symptoms  Cough 12  Haemoptysis 11  Productive cough 33  Sputum discoloured 11  Laryngeal spasm, oedema and obstruction  Stridor 11  Lower respiratory tract signs and symptoms  Hiccups 11  Nasal disorders NEC  Epistaxis 22  Neonatal hypoxic conditions  Brief resolved unexplained event 11  Infantile apnoea 33  Neonatal hypoxia 11  Respiratory signs and symptoms NEC  Use of accessory respiratory muscles 11  Upper respiratory tract signs and symptoms  Choking 11  Condition 31  Condition 32  Condition 33  Condition 34  Condition 34  Condition 35  Condition 36  Condition 36  Condition 37  C			0
Bronchospasm and obstruction Wheezing Conditions associated with abnormal gas exchange Cyanosis central Respiratory acidosis Coughing and associated symptoms Cough Haemoptysis Productive cough Sputum discoloured Laryngeal spasm, oedema and obstruction Stridor Lower respiratory tract signs and symptoms Hiccups Nasal disorders NEC Epistaxis Pief resolved unexplained event Infantile apnoea Neonatal hypoxia Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia	Respiratory distress	2	0
Wheezing  Conditions associated with abnormal gas exchange  Cyanosis central Respiratory acidosis  Coughing and associated symptoms  Cough Haemoptysis Productive cough Sputum discoloured Laryngeal spasm, oedema and obstruction Stridor Stridor Lower respiratory tract signs and symptoms Hiccups Nasal disorders NEC Epistaxis Veonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia	Tachypnoea	1	0
Conditions associated with abnormal gas exchange Cyanosis central Respiratory acidosis  Coughing and associated symptoms Cough Haemoptysis Productive cough Sputum discoloured Laryngeal spasm, oedema and obstruction Stridor Lower respiratory tract signs and symptoms Hiccups Nasal disorders NEC Epistaxis Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia	Bronchospasm and obstruction		
Cyanosis central Respiratory acidosis  Coughing and associated symptoms Cough Haemoptysis Productive cough Sputum discoloured Laryngeal spasm, oedema and obstruction Stridor Lower respiratory tract signs and symptoms Hiccups Nasal disorders NEC Epistaxis Prief resolved unexplained event Infantile apnoea Neonatal hypoxia Respiratory signs and symptoms NEC Use of accessory respiratory muscles Choking Dysphonia	Wheezing	3	0
Respiratory acidosis  Coughing and associated symptoms  Cough Haemoptysis Productive cough Sputum discoloured  Laryngeal spasm, oedema and obstruction Stridor Stridor  Lower respiratory tract signs and symptoms Hiccups Hiccups Nasal disorders NEC Epistaxis 2 Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia	Conditions associated with abnormal gas exchange		
Respiratory acidosis  Coughing and associated symptoms  Cough Haemoptysis Productive cough Sputum discoloured  Laryngeal spasm, oedema and obstruction Stridor Stridor  Lower respiratory tract signs and symptoms Hiccups Hiccups Nasal disorders NEC Epistaxis 2 Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia	Cyanosis central	1	0
Cough 12 Haemoptysis 1 Productive cough 3 Sputum discoloured 1  Laryngeal spasm, oedema and obstruction Stridor 1  Lower respiratory tract signs and symptoms Hiccups 1  Nasal disorders NEC Epistaxis 2  Neonatal hypoxic conditions Brief resolved unexplained event 1 Infantile apnoea 3 Neonatal hypoxia 1  Respiratory signs and symptoms NEC Use of accessory respiratory muscles 1  Upper respiratory tract signs and symptoms Choking 1 Dysphonia 1		1	0
Cough Haemoptysis Haemoptysis Productive cough Sputum discoloured Laryngeal spasm, oedema and obstruction Stridor Lower respiratory tract signs and symptoms Hiccups Hiccups 1 Nasal disorders NEC Epistaxis 2 Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia			
Haemoptysis 1 Productive cough 3 Sputum discoloured 1  Laryngeal spasm, oedema and obstruction Stridor 1  Lower respiratory tract signs and symptoms Hiccups 1  Nasal disorders NEC Epistaxis 2  Neonatal hypoxic conditions Brief resolved unexplained event 1 Infantile apnoea 3 Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles 1  Upper respiratory tract signs and symptoms Choking Dysphonia 1		12	0
Productive cough Sputum discoloured  Laryngeal spasm, oedema and obstruction Stridor  Lower respiratory tract signs and symptoms Hiccups  Nasal disorders NEC Epistaxis  Productive cough Stridor  Lower respiratory tract signs and symptoms Hiccups  Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia		1	0
Sputum discoloured  Laryngeal spasm, oedema and obstruction Stridor  Lower respiratory tract signs and symptoms Hiccups  Nasal disorders NEC Epistaxis  Peonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia		3	
Laryngeal spasm, oedema and obstruction Stridor  Lower respiratory tract signs and symptoms Hiccups Hiccups  Nasal disorders NEC Epistaxis  2 Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia		1	0
Stridor  Lower respiratory tract signs and symptoms  Hiccups  Nasal disorders NEC  Epistaxis  2  Neonatal hypoxic conditions  Brief resolved unexplained event  Infantile apnoea  Neonatal hypoxia  Respiratory signs and symptoms NEC  Use of accessory respiratory muscles  Upper respiratory tract signs and symptoms  Choking  Dysphonia			
Lower respiratory tract signs and symptoms Hiccups Nasal disorders NEC Epistaxis 2 Neonatal hypoxic conditions Brief resolved unexplained event Infantile apnoea Neonatal hypoxia 1 Respiratory signs and symptoms NEC Use of accessory respiratory muscles 1 Upper respiratory tract signs and symptoms Choking Dysphonia		1	0
Hiccups  Nasal disorders NEC  Epistaxis  Neonatal hypoxic conditions  Brief resolved unexplained event Infantile apnoea Neonatal hypoxia  Respiratory signs and symptoms NEC Use of accessory respiratory muscles  Upper respiratory tract signs and symptoms Choking Dysphonia	Lower respiratory tract signs and symptoms		
Nasal disorders NEC  Epistaxis  Neonatal hypoxic conditions  Brief resolved unexplained event Infantile apnoea Neonatal hypoxia 1 Respiratory signs and symptoms NEC Use of accessory respiratory muscles Upper respiratory tract signs and symptoms Choking Dysphonia		1	0
Epistaxis 2  Neonatal hypoxic conditions  Brief resolved unexplained event 1 Infantile apnoea 3 Neonatal hypoxia 1  Respiratory signs and symptoms NEC Use of accessory respiratory muscles 1 Upper respiratory tract signs and symptoms Choking 1 Dysphonia 1			
Neonatal hypoxic conditionsBrief resolved unexplained event1Infantile apnoea3Neonatal hypoxia1Respiratory signs and symptoms NECUse of accessory respiratory muscles1Upper respiratory tract signs and symptoms1Choking1Dysphonia1		2	0
Brief resolved unexplained event 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
Infantile apnoea 3 Neonatal hypoxia 1 Respiratory signs and symptoms NEC Use of accessory respiratory muscles 1 Upper respiratory tract signs and symptoms Choking 1 Dysphonia 1		1	0
Neonatal hypoxia  Respiratory signs and symptoms NEC  Use of accessory respiratory muscles  Upper respiratory tract signs and symptoms  Choking  Dysphonia  1  1  1  1  1  1  1  1  1  1  1  1  1		3	0
Respiratory signs and symptoms NECUse of accessory respiratory muscles1Upper respiratory tract signs and symptoms1Choking1Dysphonia1			0
Use of accessory respiratory muscles 1  Upper respiratory tract signs and symptoms Choking 1  Dysphonia 1			
Upper respiratory tract signs and symptoms1Choking1Dysphonia1		1	0
Choking 1 0		·	
Dysphonia 1 (		1	0
		1	0
	Oropharyngeal pain	2	0
		1	0
	Respiratory disorders SOC TOTAL	80	ŏ

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.1		
Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Cold sweat	2	0
Hyperhidrosis	3	
Bullous conditions		
Blister	4	0
Dermatitis bullous	1	l o
Pemphigoid	1	l o
Dermal and epidermal conditions NEC		
Dry skin	4	0
Papule	3	l о
Skin burning sensation	1	0
Skin discolouration	14	
Skin disorder	1	0
Skin induration	1	l о
Skin lesion	1	0
Skin plaque	1	l о
Skin reaction	2	0
Skin warm	6	l о
Skin weeping	1	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	4	0
Dermatitis atopic	1	0
Dermatitis diaper	1	0
Eczema	12	
Eczema infantile	1	0
Dermatitis ascribed to specific agent		
Palmar-plantar erythrodysaesthesia syndrome	1	0
Erythemas		
Erythema	36	0
Exfoliative conditions		
Skin exfoliation	1	0
Pruritus NEC		
Pruritus	7	0
Purpura and related conditions		
Petechiae	12	0
Purpura	2	0
Rashes, eruptions and exanthems NEC		
Rash	57	0
Rash erythematous	14	
Rash macular	15	0
Rash papular	7	
Rash pruritic		
Rash vesicular	3 5	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin vasomotor conditions		
Livedo reticularis	11	0
Lividity	1	o
Urticarias		
Urticaria	22	0

### Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria chronic	1	0
Urticaria pressure	1	0
Skin disorders SOC TOTAL	264	0

#### Name: Infanrix Hexa Vaccine Analysis Print

Reaction Name	Total	Fatal
Surgical & medical procedures		
Therapeutic procedures NEC		
Injection	1	0
Surgical & medical procedures SOC TOTAL	1	l o

Reaction Name	Total	Fatal
Vascular disorders	Iolai	i alai
Arterial infections and inflammations		
	4	4
Kawasaki's disease	1	1
Circulatory collapse and shock	0	0
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	12	0
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	5	0
Poor peripheral circulation	1	0
Site specific vascular disorders NEC		
Pallor	43	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular disorders SOC TOTAL	68	1
TOTAL REACTIONS FOR DRUG	1740	17
TOTAL REPORTS	622	
TOTAL FATAL OUTCOME REPORTS		17