### Case Series Drug Analysis Print Name: FOI 24/202- Priorix Vaccine Analysis Print

Report Run Date:08-Mar-2024Data Lock Date:08-Mar-2024 05:45:42Earliest Reaction Date:11-Mar-1997MedDRA Version:MedDRA 26.1

FOI 24/202- Priorix All UK spontaneous suspected Adverse Drug Reaction Vaccine Analysis Print: (ADR) reports associated with the Priorix vaccine up to and including 07/03/2024

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		-
Reaction Name	<u> </u>	<u>Fatal</u>
Blood disorders		
Bleeding tendencies		
Increased tendency to bruise	1	0
Coagulopathies		
Antiphospholipid syndrome	1	0
Leukocytoses NEC		
Monocytosis	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	11	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Spleen disorders		
Splenomegaly	1	0
Thrombocytopenias		
Immune thrombocytopenia	3	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	20	0

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Describer Marris	Tatal	Fatal
Reaction Name	<u> </u>	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	2	0
Noninfectious myocarditis		
Myocarditis	1	1
Rate and rhythm disorders NEC		
Bradycardia	2	0
Tachycardia	2	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	2	1
Cardio-respiratory arrest	1	0
Cardiac disorders SOC TOTAL	10	2

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Reaction Name	Tota		Fatal
Congenital disorders			
Cerebellar disorders congenital			
Hereditary ataxia		1	C
Connective tissue disorders congenital			
Hypermobility syndrome		1	C
Lymphatic system disorders congenital			
Lymphatic malformation		1	1
Congenital disorders SOC TOTAL		3	1

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear congestion	1	0
Ear discomfort	1	0
Ear pain	4	0
Ear swelling	1	0
Hearing losses		
Deafness	4	0
Deafness unilateral	1	0
Hyperacusia		
Hyperacusis	1	0
Inner ear signs and symptoms		
Tinnitus	2	0
Vertigo	1	0
Ear disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	2	0
Ocular disorders NEC		
Eye disorder	1	0
Eye pain	4	0
Eye swelling	6	0
Ocular infections, inflammations and associated manifestations		
Eye discharge	2	0
Eye irritation	1	0
Eye pruritus	1	0
Ocular hyperaemia	5	0
Ocular nerve and muscle disorders		
Eye movement disorder	5	0
Ocular sensation disorders		
Photophobia	4	0
Pupil disorders		
Mydriasis	1	0
Pupil fixed	1	0
Eve disorders SOC TOTAL	33	0

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Earliest Reaction Date: 11-Mar-1997 Reaction Name	Total	Fatal
Gastrointestinal disorders		
Dental disorders NEC		
Tooth disorder	1	C
Diarrhoea (excl infective)		-
Diarrhoea	26	C
Diarrhoea haemorrhagic	1	
Faecal abnormalities NEC		
Faeces discoloured	1	C
Flatulence, bloating and distension		
Abdominal distension	2	C
Flatulence	1	c
Gastrointestinal and abdominal pains (ex	cl oral and throat)	
Abdominal pain	, 7	( C
Abdominal pain upper	7	C
Gastrointestinal atonic and hypomotility d	lisorders NEC	
Constipation	4	C
Gastrointestinal disorders NEC		
Gastrointestinal disorder	1	C
Gastrointestinal signs and symptoms NE	C	
Abdominal discomfort	3	C
Anal incontinence	2	C C
Gingival disorders, signs and symptoms I	NEC	
Gingival swelling	1	C
Intestinal haemorrhages		
Rectal haemorrhage	2	c c
Nausea and vomiting symptoms		
Nausea	14	. C
Vomiting	33	C
Vomiting projectile	2	C C
Non-site specific gastrointestinal haemor	rhages	
Haematemesis	- 1	C
Oral dryness and saliva altered		
Salivary hypersecretion	1	C
Oral soft tissue disorders NEC		
Chapped lips	2	C C
Oral disorder	1	C
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	C
Oral soft tissue signs and symptoms		
Oral mucosal eruption	1	C
Oral pain	1	C
Paraesthesia oral	1	C
Oral soft tissue swelling and oedema		
Lip swelling	6	C
Mouth swelling	2	0
Rectal inflammations NEC		
Proctitis	1	C
Salivary gland disorders NEC		
Salivary gland pain	1	(
Salivary gland enlargements		
Parotid gland enlargement	7	. (
Stomatitis and ulceration		
Stomatitis	1	
Tongue signs and symptoms		

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Reaction Name		Total	Fatal
Gastrointestinal disorders contestinal disorders c	ont'd		
Swollen tongue		1	0
Gastrointestinal disorders SOC TOTAL		136	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site rash		1 C
Asthenic conditions		
Asthenia		e o
Fatigue	1:	
Malaise	3	
Death and sudden death		
Death		2 2
Sudden death		1 1
Sudden infant death syndrome		1 1
Febrile disorders		
Pyrexia	11	7 C
Feelings and sensations NEC		
Chills		3 0
Feeling abnormal		2 0
Feeling drunk		1 0
Feeling hot	1:	
Feeling of body temperature change		2 0
Hangover		1 0
Thirst decreased		1 0
Gait disturbances		
Gait disturbance		5 0
Gait inability		6 0
General signs and symptoms NEC		
Condition aggravated		1 0
Crepitations		1 0
Crying	1	
Developmental delay		1 0
Developmental regression		4 0
General physical health deterioration		1 0
High-pitched crying		1 0
III-defined disorder		1 0
Illness		4 0
Induration		1 0
Influenza like illness		4 C
Local reaction	1:	5 0
Peripheral swelling	3	
Screaming		B C
Swelling	1.	
Swelling face	1:	
Inflammations		
Inflammation		7 C
Infusion site reactions		-
Infusion site erythema		1 C
Injection site reactions		
Injection site bruising		2 0
Injection site eczema		1 0
Injection site erythema	11	-
Injection site induration		1 C
Injection site inflammation		4 C
Injection site mass		4 C
Injection site pain		5 0
Injection site pain Injection site pruritus		3 C

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site rash	1	0
Injection site reaction	14	. 0
Injection site swelling	15	0
Injection site warmth	1	0
Oedema NEC		
Oedema peripheral	3	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	3	0
Discomfort	5	0
Facial pain	1	0
Pain	12	2 0
Tenderness	4	. 0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Therapy non-responder	2	2 0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	2 0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	g	0
Vaccination site inflammation	1	0
Vaccination site joint erythema	1	0
Vaccination site mass	2	2 0
Vaccination site pain	4	. 0
Vaccination site pruritus	2	2 0
Vaccination site rash	4	. 0
Vaccination site reaction	1	0
Vaccination site swelling	11	0
Vaccination site vesicles	1	0
Vaccination site warmth	4	-
General disorders SOC TOTAL	479	4

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Reaction Name		Total	Fatal
Hepatic disorders			
Cholestasis and jaundice			
Jaundice		2	0
Hepatic disorders SOC TOTAL		2	0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema	1	0
Hypersensitivity	10	0
Multiple allergies	1	0
Allergies to foods, food additives, drugs and other chemicals		
Allergic reaction to excipient	1	0
Drug hypersensitivity	1	0
Food allergy	1	0
Reaction to excipient	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	15	0
Immune system disorders SOC TOTAL	31	0

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	edDRA Version: MedDRA 26.1	Eatal
Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Cellulitis	21	1
Injection site cellulitis		
Skin bacterial infection	1	0
Vaccination site cellulitis	2	2  C
Candida infections		
Candida infection	1	0
Vulvovaginal candidiasis	1	0
Central nervous system and spinal infections		
Encephalitis	3	1
Encephalitis brain stem	1	0
Meningitis	2	2 C
Myelitis	1	0
Dental and oral soft tissue infections		
Parotitis	4	l o
Ear infections		
Ear infection	3	
Eye and eyelid infections		
Conjunctivitis	5	
Eye infection	1	
Fungal infections NEC		
Fungal skin infection	1	0
Infections NEC		
Abscess	1	
Infection	1	0
Injection site infection		0
Toxic shock syndrome		
Vaccination site infection	1	0
Influenza viral infections		
Influenza	1	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	3	6 C
Male reproductive tract infections		
Orchitis	2	2 0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0
Mumps viral infections		
Mumps	7	' C
Rubeola viral infections		
Measles	5	i C
Sepsis, bacteraemia, viraemia and fungaemia I	NEC	
Sepsis	1	
Septic shock	1	
Tuberculous infections		
Erythema induratum	2	
Tuberculosis	1	
Upper respiratory tract infections		
Nasopharyngitis	3	
Rhinitis	1	
Tonsillitis	5	
	5	
Upper respiratory tract infection	5	
Urinary tract infections		
Urinary tract infection	2	<u>2 C</u>

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<b>Reaction Name</b>			Total	Fatal
Infections	Infections cont'd			
Viral infections N	EC			
Meningitis viral			1	0
Infections SOC TO	TAL		100	1

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Reaction Name	Total	Fatal
Injuries		
Cerebral injuries NEC		
Craniocerebral injury	1	C
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	4	C
Foetal exposure during pregnancy	1	C
Maternal exposure before pregnancy	2	C
Maternal exposure timing unspecified	1	C
Medication errors, product use errors and issues NEC		
Inadequate aseptic technique in use of product	1	C
Medication error	1	C
Non-site specific injuries NEC		
Fall	1	C
Product administration errors and issues		
Contraindicated product administered	1	C
Expired product administered	2	C
Extra dose administered	1	C
Inappropriate schedule of product administration	2	C
Product administered to patient of inappropriate age	1	C
Product monitoring errors and issues		
Labelled drug-disease interaction medication error	1	C
Product storage errors and issues in the product use system		
Product storage error	1	C
Skin injuries NEC		
Contusion	4	C
Vaccination related complications		
Immunisation reaction	1	0
Injuries SOC TOTAL	26	C

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Investigations		
Autoimmunity analyses		
Rheumatoid factor increased	1	0
Blood gas and acid base analyses		
Oxygen saturation decreased	2	0
Digestive enzymes		
Amylase increased	1	0
Haematological analyses NEC		
Red blood cell sedimentation rate increased	2	0
Heart rate and pulse investigations		
Heart rate decreased	3	0
Heart rate increased	1	0
Heart rate irregular	1	0
Pulse abnormal	2	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Physical examination procedures and organ system status		
Body temperature decreased	2	0
Body temperature fluctuation	3	0
Body temperature increased	15	0
Respiratory rate increased	2	0
Weight decreased	1	0
Platelet analyses		
Platelet count abnormal	1	0
Platelet count decreased	1	0
Protein analyses NEC		
C-reactive protein increased	2	0
Toxicology laboratory analyses		
Heavy metal increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	1	0
Blood pressure increased	3	0
Investigations SOC TOTAL	46	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	22	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Food intolerance	3	0
General nutritional disorders NEC		
Feeding disorder	2	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Metabolic disorders SOC TOTAL	30	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis		
Arthropathy	1	0
Bone related signs and symptoms		
Bone pain	1	0
Joint related signs and symptoms		
Arthralgia	17	0
Joint stiffness	2	0
Joint swelling	4	0
Lupus erythematosus (incl subtypes)		-
Systemic lupus erythematosus	1	0
Muscle pains		
Myalgia	4	0
Muscle related signs and symptoms NEC		
Muscle spasms	2	0
Muscle tightness	1	0
Muscle tone abnormalities		
Floppy infant	3	0
Muscle rigidity	3	0
Muscle weakness conditions		
Muscular weakness	3	0
Musculoskeletal and connective tissue conditions NEC		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Posture abnormal	2	0
Weight bearing difficulty	3	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	4	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Neck pain	3	C
Pain in extremity	18	0
Soft tissue disorders NEC		
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	81	

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Reaction Name		<u>Total</u>	Fatal
Nervous system disorders Absence seizures			
		4	0
Petit mal epilepsy	150	4	C
Central nervous system vascular disorders N		1	0
Brain hypoxia Coordination and balance disturbances		1	0
		4	0
Ataxia Balance disorder		1	0
		3	0
Coordination abnormal		1	0
Dysstasia		1	0
Hand-eye coordination impaired		1	0
Cortical dysfunction NEC		4	0
Aphasia		4	0
Dyslexia		1	0
Dyspraxia		2	0
Disturbances in consciousness NEC		0	0
Depressed level of consciousness		2	0
Lethargy		19	0
Loss of consciousness		11	0
Somnolence		16	0
Syncope		21	0
Dyskinesias and movement disorders NEC			0
Clumsiness		1	0
Dyskinesia		3	0
Hypokinesia		1	0
Psychomotor hyperactivity		3	0
Facial cranial nerve disorders			-
Facial paralysis		1	0
Generalised tonic-clonic seizures		0	0
Generalised tonic-clonic seizure		2	0
Headaches NEC		0.4	0
Headache		24	0
Sinus headache		1	0
Intellectual disabilities			0
Intellectual disability		1	0
Lumbar spinal cord and nerve root disorders			0
Sciatica		1	0
Mental impairment (excl dementia and mem	ory loss)	0	0
Disturbance in attention		2	0
Mental impairment		1	0
Muscle tone abnormal		C	0
Hypotonia		6	0
Narcolepsy and hypersomnia		0	0
Hypersonnia		2	0
Nervous system disorders NEC		0	0
Nervous system disorder		2	0
Neurological signs and symptoms NEC		10	-
Dizziness		10	0
Dizziness postural		1	C
Inability to crawl		1	0
Meningism		1	C
Myoclonus		1	0
Neurological symptom		1	C
Presyncope		4	C

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Reaction Name		Total	Fatal
Nervous system disordersus system disorders of	cont'd		
Unresponsive to stimuli		5	0
Neuromuscular disorders NEC			
Hypotonic-hyporesponsive episode		2	0
Olfactory nerve disorders			
Anosmia		1	0
Paraesthesias and dysaesthesias			
Hypoaesthesia		7	0
Paraesthesia		7	0
Paralysis and paresis (excl cranial nerve)			
Paralysis		1	0
Seizures and seizure disorders NEC			
Epilepsy		2	0
Febrile convulsion		10	0
Myoclonic epilepsy		1	0
Partial seizures		2	0
Seizure		17	0
Seizure like phenomena		1	0
Sensory abnormalities NEC			
Dysgeusia		1	0
Speech and language abnormalities			
Dysarthria		1	0
Speech disorder		4	0
Speech disorder developmental		1	0
Structural brain disorders NEC			
Brain injury		1	0
Tremor (excl congenital)			
Tremor		9	0
Nervous system disorders SOC TOTAL		231	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	5	0
Gestational age and weight conditions		
Premature baby	1	0
Normal pregnancy, labour and delivery		
Live birth	1	0
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Product quality issues NEC		
Product complaint	3	0
null SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	6	c d
Behaviour disorder	2	c
Breath holding	1	C C
Staring	1	C C
Anxiety symptoms		
Agitation	2	C
Anxiety	5	
Nervousness	3	1
Stress	1	C C
Behaviour and socialisation disturbances		
Aggression	3	C
Antisocial behaviour	1	C
Personality change	1	
Social avoidant behaviour	2	1
Confusion and disorientation		
Confusional state	2	C
Disorientation	4	
Deliria		-
Delirium	3	C
Depressive disorders		
Depression	2	C
Disturbances in initiating and maintaining		
Insomnia	6	C
Dyssomnias		
Poor quality sleep	1	C
Emotional and mood disturbances NEC		
Emotional distress	3	C
Irritability	15	
Mood altered	1	
Fear symptoms and phobic disorders (incl	social phobia)	-
Fear	1	C
Social anxiety disorder	1	
Hallucinations (excl sleep-related)		-
Hallucination	2	C
Increased physical activity levels		
Restlessness	5	c c
Learning disorders		
Learning disability	1	c d
Mental disorders NEC		-
Mental disorder	1	c d
Mood alterations with depressive symptom	ns	_
Depressed mood	3	C C
Tearfulness	1	
Mood disorders NEC		
Listless	2	C
Obsessive-compulsive disorders and sym		
Obsessive-compulsive symptom	1	0
Panic attacks and disorders		
Panic attack	1	
Parasomnias		
Sleep terror	1	
Pervasive developmental disorders NEC		

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Reaction Name		Total	Fatal
Psychiatric disordersPsychiatric disorders cont'd			
Autism spectrum disorder		12	0
Psychiatric symptoms NEC			
Decreased eye contact		1	0
Sleep disorders NEC			
Sleep disorder		2	0
Speech articulation and rhythm disturbance	S		
Dysphemia		1	0
Lack of spontaneous speech		1	0
Psychiatric disorders SOC TOTAL		102	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Incontinence	1	C
Urinary incontinence	3	C
Urinary abnormalities		
Chromaturia	1	0
Haematuria	1	0
Renal & urinary disorders SOC TOTAL	6	

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Laniest Reaction Date. 11-Mai-1997 MedDRA Version. MedDRA 20.1		
Reaction Name	Total	Fatal
Reproductive & breast disorders		
Erection and ejaculation conditions and disorders		
Erectile dysfunction	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	1	0
Reproductive tract signs and symptoms NEC		
Genital pain	1	0
Scrotal disorders NEC		
Scrotal swelling	1	0
Testicular and epididymal disorders NEC		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dysphoea	12	0
Respiration abnormal	1	0
Respiratory arrest	4	1
Respiratory depression	1	0
Tachypnoea	1	0
Bronchospasm and obstruction		
Asthma	1	0
Wheezing	4	0
Conditions associated with abnormal gas exchange		
Asphyxia	1	0
Coughing and associated symptoms		
Cough	13	0
Productive cough	1	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Nasal disorders NEC		
Epistaxis	3	0
Nasal pruritus	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	1	0
Pharyngeal swelling	2	0
Tonsillar hypertrophy	1	0
Tonsillar inflammation	2	0
Respiratory signs and symptoms NEC		
Respiratory symptom	1	0
Upper respiratory tract signs and symptoms		
Dysphonia	1	0
Oropharyngeal pain	9	0
Rhinorrhoea	3	0
Sneezing	1	0
Throat tightness	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	67	1

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	1	I 0
Angioedemas		
Angioedema	1	I O
Apocrine and eccrine gland disorders		
Cold sweat	4	1 O
Hyperhidrosis	4	1 O
Miliaria	1	l o
Night sweats	1	I o
Bullous conditions		
Blister	6	6 0
Blood blister	2	2 0
Dermatitis bullous	1	I o
Erythema multiforme	5	5 0
Stevens-Johnson syndrome	2	2 0
Dermal and epidermal conditions NEC		
Dry skin	2	2 0
Papule	1	I 0
Scab	1	I 0
Skin burning sensation	1	I 0
Skin discolouration	2	2 0
Skin disorder	2	2 0
Skin lesion	2	2 0
Skin reaction	7	7 0
Skin warm	7	7 0
Dermatitis and eczema		
Dermatitis	1	I 0
Dermatitis allergic	1	I 0
Dermatitis atopic	1	0 0
Eczema	7	7 0
Eczema infantile	2	2 0
Erythemas		
Erythema	33	3 0
Exfoliative conditions		
Skin exfoliation	1	0 0
Panniculitides		
Erythema nodosum	1	0 0
Pigmentation changes NEC		
Pigmentation disorder	1	0 0
Pruritus NEC		
Pruritus	24	1 O
Psoriatic conditions		
Guttate psoriasis	1	0 0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0 0
Petechiae	4	1 O
Rashes, eruptions and exanthems NEC		
Rash	73	3 0
Rash erythematous	ç	
Rash macular	16	6 C
Rash maculo-papular	12	2 0
Rash morbilliform	12	
Rash papular	6	

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash pruritic	6	0
Rash rubelliform	1	0
Rash scarlatiniform	1	0
Rash vesicular	3	0
Urticarias		
Urticaria	26	0
Skin disorders SOC TOTAL	296	0

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Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Bedridden	1	0
Immobile	1	0
Impaired work ability	1	0
Educational issues		
Educational problem	1	0
Social circumstances SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Induced abortions		
Abortion induced	3	0
Surgical & medical procedures SOC TOTAL	3	<b>)</b> 0

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Reaction Name	Total	Fatal
Vascular disorders		
Arterial infections and inflammations		
Giant cell arteritis	1	C
Kawasaki's disease	1	C
Circulatory collapse and shock		
Circulatory collapse	3	C
Shock	2	C
Haemorrhages NEC		
Haemorrhage	1	C
Peripheral vascular disorders NEC		
Cyanosis	5	C
Flushing	3	C
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	2	C
Poor peripheral circulation	1	C
Site specific vascular disorders NEC		
Pallor	25	C
Vascular hypertensive disorders NEC		
Hypertension	1	C
Vascular hypotensive disorders		
Hypotension	1	C
Vascular disorders SOC TOTAL	46	( C
TOTAL REACTIONS FOR DRUG	1785	g
TOTAL REPORTS	580	
TOTAL FATAL OUTCOME REPORTS		9