

Case Series Drug Analysis Print

Name: FOI 23/945 - Priorix Vaccine Analysis Print

Report Run Date: 20-Dec-2023

Data Lock Date: 07-Dec-2023 18:30:03

Earliest Reaction Date: 11-Mar-1997

MedDRA Version: MedDRA 26.1

FOI 23/945 - Priorix All UK spontaneous suspected Adverse Drug Reaction
Vaccine Analysis Print: (ADR) reports associated with the Priorix vaccine up to
and including 07/12/2023.

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

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

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	1	0
<i>Lymphatic system disorders congenital</i>		
Lymphatic malformation	1	1
Congenital disorders SOC TOTAL	3	1

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

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

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	26	0
Diarrhoea haemorrhagic	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	7	0
Abdominal pain upper	7	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
Anal incontinence	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	13	0
Vomiting	32	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
Oral disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal eruption	1	0
Oral pain	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
Mouth swelling	2	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	7	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	132	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	9	0
Fatigue	17	0
Malaise	35	0
<i>Death and sudden death</i>		
Death	2	2
Sudden death	1	1
Sudden infant death syndrome	1	1
<i>Febrile disorders</i>		
Pyrexia	114	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling abnormal	2	0
Feeling drunk	1	0
Feeling hot	12	0
Feeling of body temperature change	2	0
Hangover	1	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	6	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	9	0
Developmental delay	1	0
Developmental regression	3	0
General physical health deterioration	1	0
High-pitched crying	1	0
Ill-defined disorder	1	0
Illness	4	0
Induration	1	0
Influenza like illness	4	0
Local reaction	15	0
Peripheral swelling	31	0
Screaming	8	0
Swelling	14	0
Swelling face	12	0
<i>Inflammations</i>		
Inflammation	7	0
<i>Infusion site reactions</i>		
Infusion site erythema	1	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site eczema	1	0
Injection site erythema	18	0
Injection site induration	1	0
Injection site inflammation	4	0
Injection site mass	3	0
Injection site pain	5	0
Injection site pruritus	3	0

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General disorders General disorders cont'd		
Injection site rash	1	0
Injection site reaction	14	0
Injection site swelling	14	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	4	0
Facial pain	1	0
Pain	12	0
Tenderness	4	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Therapy non-responder	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	9	0
Vaccination site inflammation	1	0
Vaccination site joint erythema	1	0
Vaccination site mass	2	0
Vaccination site pain	4	0
Vaccination site pruritus	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	0
General disorders SOC TOTAL	469	4

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	10	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
Food allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	15	0
Immune system disorders SOC TOTAL	30	0

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Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	20	0
Injection site cellulitis	7	0
Skin bacterial infection	1	0
Vaccination site cellulitis	2	0
<i>Candida infections</i>		
Candida infection	1	0
Vulvovaginal candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	1
Encephalitis brain stem	1	0
Meningitis	2	0
Myelitis	1	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	4	0
<i>Ear infections</i>		
Ear infection	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	5	0
Eye infection	1	0
<i>Fungal infections NEC</i>		
Fungal skin infection	1	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	1	0
Injection site infection	1	0
Toxic shock syndrome	1	0
Vaccination site infection	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	0
<i>Male reproductive tract infections</i>		
Orchitis	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	7	0
<i>Rubeola viral infections</i>		
Measles	5	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Septic shock	1	0
<i>Tuberculous infections</i>		
Erythema induratum	2	0
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Rhinitis	1	0
Tonsillitis	5	0
Upper respiratory tract infection	5	0
<i>Urinary tract infections</i>		
Urinary tract infection	2	0

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Reaction Name		Total	Fatal
Infections	Infections cont'd		
<i>Viral infections NEC</i>			
Meningitis viral		1	0
Infections SOC TOTAL		99	1

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Injuries		
<i>Cerebral injuries NEC</i>		
Craniocerebral injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	1	0
Maternal exposure before pregnancy	2	0
Maternal exposure timing unspecified	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Product administration errors and issues</i>		
Contraindicated product administered	1	0
Expired product administered	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	2	0
Product administered to patient of inappropriate age	1	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
<i>Vaccination related complications</i>		
Immunisation reaction	1	0
Injuries SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Rheumatoid factor increased	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	3	0
Heart rate increased	1	0
Heart rate irregular	1	0
Pulse abnormal	2	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	2	0
Body temperature fluctuation	3	0
Body temperature increased	15	0
Respiratory rate increased	2	0
Weight decreased	1	0
<i>Platelet analyses</i>		
Platelet count abnormal	1	0
Platelet count decreased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	2	0
<i>Toxicology laboratory analyses</i>		
Heavy metal increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
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		
<i>Appetite disorders</i>		
Decreased appetite	20	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	3	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	2	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
Metabolic disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	17	0
Joint stiffness	2	0
Joint swelling	4	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Myalgia	4	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle tightness	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	3	0
Muscle rigidity	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	3	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Posture abnormal	1	0
Weight bearing difficulty	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Neck pain	3	0
Pain in extremity	17	0
<i>Soft tissue disorders NEC</i>		
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	79	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	4	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	3	0
Coordination abnormal	1	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
Dyslexia	1	0
Dyspraxia	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	18	0
Loss of consciousness	11	0
Somnolence	16	0
Syncope	21	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	3	0
Hypokinesia	1	0
Psychomotor hyperactivity	3	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Headache	23	0
Sinus headache	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
Mental impairment	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	6	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	9	0
Dizziness postural	1	0
Inability to crawl	1	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders 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	6	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	227	0

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

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

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
Behaviour disorder	2	0
Breath holding	1	0
Staring	1	0
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	5	0
Nervousness	3	0
Stress	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
Antisocial behaviour	1	0
Personality change	1	0
Social avoidant behaviour	2	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	4	0
<i>Deliria</i>		
Delirium	3	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	6	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	3	0
Irritability	14	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Social anxiety disorder	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
<i>Increased physical activity levels</i>		
Restlessness	5	0
<i>Learning disorders</i>		
Learning disability	1	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	3	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric 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 disturbances		
Dysphemia	1	0
Lack of spontaneous speech	1	0
Psychiatric disorders SOC TOTAL	100	0

Case Series Drug Analysis Print

Name: FOI 23/945 - Priorix Vaccine Analysis Print

Report Run Date: 20-Dec-2023

Data Lock Date: 07-Dec-2023 18:30:03

Earliest Reaction Date: 11-Mar-1997

MedDRA Version: MedDRA 26.1

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

Case Series Drug Analysis Print

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Earliest Reaction Date: 11-Mar-1997

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	12	0
Respiration abnormal	1	0
Respiratory arrest	4	1
Respiratory depression	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	4	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	12	0
Productive cough	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	3	0
Nasal pruritus	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	1	0
Tonsillar hypertrophy	1	0
Tonsillar inflammation	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Oropharyngeal pain	9	0
Rhinorrhoea	3	0
Sneezing	1	0
Throat tightness	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	64	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	4	0
Miliaria	1	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	6	0
Blood blister	2	0
Dermatitis bullous	1	0
Erythema multiforme	5	0
Stevens-Johnson syndrome	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Papule	1	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	2	0
Skin disorder	2	0
Skin lesion	2	0
Skin reaction	7	0
Skin warm	7	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	1	0
Dermatitis atopic	1	0
Eczema	7	0
Eczema infantile	2	0
<i>Erythemas</i>		
Erythema	33	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	23	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	72	0
Rash erythematous	8	0
Rash macular	15	0
Rash maculo-papular	12	0
Rash morbilliform	12	0
Rash papular	6	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
Rash pruritic		5	0
Rash rubelliform		1	0
Rash scarlatiniform		1	0
Rash vesicular		3	0
<i>Urticarias</i>			
Urticaria		26	0
Skin disorders SOC TOTAL		291	0

Case Series Drug Analysis Print

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

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

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	5	0
Flushing	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	25	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	45	0
TOTAL REACTIONS FOR DRUG	1748	9
TOTAL REPORTS	570	
TOTAL FATAL OUTCOME REPORTS		9