

**Case Series Drug Analysis Print**  
**Name: FOI 21/636 Priorix vaccine**

Report Run Date: 25-Jun-2021  
Data Lock Date: 24-Jun-2021 18:30:03  
Earliest Reaction Date: 11-Mar-1997  
MedDRA Version: MedDRA 24.0  
FOI 21/636 Priorix vaccine: All UK spontaneous suspected ADR reports associated with Priorix received up to and including 24 June 2021

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<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	10	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
<b>Blood disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Cardiac disorders</b>		
<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
<b>Cardiac disorders SOC TOTAL</b>	<b>10</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	1	1
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<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
<b>Ear disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	3	0
Eye swelling	5	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	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
<b>Eye disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	24	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	31	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
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>129</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	7	0
Fatigue	16	0
Malaise	32	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	105	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
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	5	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	9	0
Developmental delay	1	0
Developmental regression	2	0
High-pitched crying	1	0
Ill-defined disorder	1	0
Illness	3	0
Induration	1	0
Influenza like illness	4	0
Local reaction	15	0
Peripheral swelling	31	0
Screaming	8	0
Swelling	13	0
Swelling face	10	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 erythema	18	0
Injection site induration	1	0
Injection site inflammation	3	0
Injection site mass	2	0
Injection site pain	5	0
Injection site pruritus	3	0
Injection site rash	1	0
Injection site reaction	14	0
Injection site swelling	14	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site warmth	1	0
<b>Oedema NEC</b>		
Oedema peripheral	3	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	1	0
Chest pain	3	0
Discomfort	3	0
Facial pain	1	0
Pain	12	0
Tenderness	4	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	1	0
Therapy non-responder	2	0
<b>Vaccination site reactions</b>		
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
<b>General disorders SOC TOTAL</b>	<b>442</b>	<b>4</b>

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

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	7	0
Multiple allergies	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Food allergy	1	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	15	0
<b>Immune system disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	20	0
Injection site cellulitis	7	0
Skin bacterial infection	1	0
Vaccination site cellulitis	2	0
<i><b>Candida infections</b></i>		
Candida infection	1	0
Vulvovaginal candidiasis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	2	1
Meningitis	2	0
<i><b>Dental and oral soft tissue infections</b></i>		
Parotitis	4	0
<i><b>Ear infections</b></i>		
Ear infection	3	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	4	0
Eye infection	1	0
<i><b>Fungal infections NEC</b></i>		
Fungal skin infection	1	0
<i><b>Infections NEC</b></i>		
Abscess	1	0
Infection	1	0
Injection site infection	1	0
Toxic shock syndrome	1	0
Vaccination site infection	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	3	0
<i><b>Male reproductive tract infections</b></i>		
Orchitis	2	0
<i><b>Molluscum contagiosum viral infections</b></i>		
Molluscum contagiosum	1	0
<i><b>Mumps viral infections</b></i>		
Mumps	7	0
<i><b>Rubeola viral infections</b></i>		
Measles	5	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
Septic shock	1	0
<i><b>Tuberculous infections</b></i>		
Erythema induratum	2	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	3	0
Rhinitis	1	0
Tonsillitis	5	0
Upper respiratory tract infection	4	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Meningitis viral	1	0
<b>Infections SOC TOTAL</b>	<b>92</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Cerebral injuries NEC</i></b>		
Craniocerebral injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	1	0
Maternal exposure before pregnancy	2	0
Maternal exposure timing unspecified	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Inadequate aseptic technique in use of product	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Fall	1	0
<b><i>Product administration errors and issues</i></b>		
Contraindicated product administered	1	0
Expired product administered	3	0
Extra dose administered	1	0
Inappropriate schedule of product administration	2	0
Product administered to patient of inappropriate age	1	0
<b><i>Product monitoring errors and issues</i></b>		
Labelled drug-disease interaction medication error	1	0
<b><i>Product storage errors and issues in the product use system</i></b>		
Product storage error	1	0
<b><i>Skin injuries NEC</i></b>		
Contusion	4	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>26</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Autoimmunity analyses</b></i>		
Rheumatoid factor increased	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	2	0
<i><b>Digestive enzymes</b></i>		
Amylase increased	1	0
<i><b>Haematological analyses NEC</b></i>		
Red blood cell sedimentation rate increased	2	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	3	0
Heart rate increased	1	0
Heart rate irregular	1	0
Pulse abnormal	2	0
<i><b>Immunoglobulin analyses</b></i>		
Blood immunoglobulin G increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature decreased	2	0
Body temperature fluctuation	3	0
Body temperature increased	14	0
Respiratory rate increased	2	0
Weight decreased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count abnormal	1	0
Platelet count decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Toxicology laboratory analyses</b></i>		
Blood heavy metal increased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	1	0
Blood pressure increased	3	0
<b>Investigations SOC TOTAL</b>	<b>45</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	18	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
<b>Metabolic disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
Arthropathy	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	16	0
Joint stiffness	1	0
Joint swelling	4	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Systemic lupus erythematosus	1	0
<i><b>Muscle pains</b></i>		
Myalgia	4	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle spasms	1	0
Muscle tightness	1	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	2	0
Muscle rigidity	3	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	3	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Posture abnormal	1	0
Weight bearing difficulty	3	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	4	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Neck pain	3	0
Pain in extremity	16	0
<i><b>Soft tissue disorders NEC</b></i>		
Neck mass	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>75</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	4	0
<i><b>Central nervous system vascular disorders NEC</b></i>		
Brain hypoxia	1	0
<i><b>Coordination and balance disturbances</b></i>		
Ataxia	1	0
Balance disorder	3	0
Coordination abnormal	1	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	4	0
Dyslexia	1	0
Dyspraxia	2	0
<i><b>Disturbances in consciousness NEC</b></i>		
Depressed level of consciousness	2	0
Lethargy	17	0
Loss of consciousness	10	0
Somnolence	15	0
Syncope	21	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Clumsiness	1	0
Dyskinesia	3	0
Hypokinesia	1	0
Psychomotor hyperactivity	3	0
<i><b>Facial cranial nerve disorders</b></i>		
Facial paralysis	1	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	2	0
<i><b>Headaches NEC</b></i>		
Headache	23	0
Sinus headache	1	0
<i><b>Lumbar spinal cord and nerve root disorders</b></i>		
Sciatica	1	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Disturbance in attention	1	0
Mental impairment	1	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	6	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Hypersomnia	2	0
<i><b>Nervous system disorders NEC</b></i>		
Nervous system disorder	2	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	8	0
Dizziness postural	1	0
Inability to crawl	1	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	4	0
Unresponsive to stimuli	5	0
<i><b>Neuromuscular disorders NEC</b></i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Hypotonic-hyporesponsive episode	2	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Hypoaesthesia	7	0
Paraesthesia	5	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paralysis	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	2	0
Febrile convulsion	6	0
Myoclonic epilepsy	1	0
Partial seizures	2	0
Seizure	16	0
Seizure like phenomena	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Dysgeusia	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	1	0
Speech disorder	4	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	9	0
<b>Nervous system disorders SOC TOTAL</b>	<b>214</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<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
<b>Pregnancy conditions SOC TOTAL</b>	<b>8</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	6	0
Behaviour disorder	2	0
Breath holding	1	0
Staring	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	5	0
Nervousness	3	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Antisocial behaviour	1	0
Social avoidant behaviour	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	2	0
Disorientation	4	0
<b><i>Deliria</i></b>		
Delirium	3	0
<b><i>Depressive disorders</i></b>		
Depression	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	5	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	3	0
Irritability	13	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
Social anxiety disorder	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	2	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	4	0
<b><i>Learning disorders</i></b>		
Learning disability	1	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	3	0
Tearfulness	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	1	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Obsessive-compulsive symptom	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	0
<b><i>Parasomnias</i></b>		
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	12	0

# Case Series Drug Analysis Print

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Report Run Date: 25-Jun-2021  
 Earliest Reaction Date: 11-Mar-1997

Data Lock Date: 24-Jun-2021 18:30:03  
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
Lack of spontaneous speech	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>96</b>	<b>0</b>

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

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Reproductive &amp; breast disorders</b>		
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	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
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>



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

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	4	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	6	0
Blood blister	2	0
Dermatitis bullous	1	0
Erythema multiforme	4	0
Stevens-Johnson syndrome	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Papule	1	0
Scab	1	0
Skin discolouration	1	0
Skin disorder	1	0
Skin lesion	2	0
Skin reaction	7	0
Skin warm	7	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis atopic	1	0
Eczema	7	0
Eczema infantile	2	0
<i>Erythemas</i>		
Erythema	32	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	19	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	65	0
Rash erythematous	7	0
Rash macular	14	0
Rash maculo-papular	12	0
Rash morbilliform	11	0
Rash papular	6	0
Rash pruritic	5	0
Rash rubelliform	1	0
Rash scarlatiniform	1	0
Rash vesicular	3	0
<i>Urticarias</i>		

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Reaction Name		Total	Fatal
<b>Skin disorders</b>	Skin disorders cont'd		
Urticaria		22	0
<b>Skin disorders SOC TOTAL</b>		<b>265</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Impaired work ability	1	0
<i>Educational issues</i>		
Educational problem	1	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Arterial infections and inflammations</b></i>		
Giant cell arteritis	1	0
Kawasaki's disease	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	3	0
Shock	2	0
<i><b>Haemorrhages NEC</b></i>		
Haemorrhage	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	5	0
Flushing	3	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	24	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1648</b>	<b>9</b>
<b>TOTAL REPORTS</b>	<b>529</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>9</b>