

Case Series Drug Analysis Print
Name: Zostavax Product Analysis Print

Report Run Date: 07-Feb-2023
Data Lock Date: 03-Feb-2023 18:30:04
Earliest Reaction Date: 12-Feb-2011
MedDRA Version: MedDRA 25.1

Zostavax Product Analysis Print: All UK, spontaneous suspected reports associated with the Zostavax vaccination, received up to and including the 20th January 2023. Date of extraction: 4th February 2023

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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	1	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Leukocytoses NEC		
Neutrophilia	1	0
Leukopenias NEC		
Lymphopenia	1	0
Lymphatic system disorders NEC		
Lymph node pain	2	0
Lymphadenopathy	10	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	16	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	1	0
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	1
Myocardial infarction	3	2
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Tachycardia	3	0
<i>Right ventricular failures</i>		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	6	0
Cardiac disorders SOC TOTAL	39	5

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	11	0
<i>Hearing disorders NEC</i>		
Dysacusis	1	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness neurosensory	3	0
Deafness unilateral	6	0
Hypoacusis	5	0
Sudden hearing loss	1	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	9	0
Vertigo	13	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	55	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Thyroid pain	1	0
Endocrine disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	4	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal lesion	1	0
Keratopathy	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
Eyelid ptosis	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	2	0
Uveitis	4	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid irritation	1	0
Swelling of eyelid	3	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye pain	13	0
Eye swelling	3	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Lens disorder	1	0
Periorbital oedema	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	3	0
Eye inflammation	2	0
Eye irritation	3	0
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	5	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	1	0
Macular detachment	1	0
Macular hole	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Cystoid macular oedema	1	0
Necrotising retinitis	1	0
<i>Visual disorders NEC</i>		
Diplopia	4	0
Halo vision	1	0
Photopsia	2	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Vision blurred	6	0
Visual impairment and blindness (excl colour blindness)		
Blindness	1	0
Blindness transient	1	0
Blindness unilateral	2	0
Visual acuity reduced	3	0
Visual impairment	6	0
Eye disorders SOC TOTAL	98	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	29	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	5	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	17	0
Abdominal pain lower	1	0
Abdominal pain upper	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
Duodenogastric reflux	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Defaecation disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Anal incontinence	1	0
Dysphagia	4	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	1	0
Gingival pain	2	0
Gingival swelling	1	0
Gingival ulceration	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	63	0
Retching	1	0
Vomiting	35	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Melaena	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	3	0
Lip dry	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Lip blister	3	0
Oral disorder	2	0
Oral lichen planus	1	0
<i>Oral soft tissue haemorrhages</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Lip pain	1	0
Oral mucosal blistering	4	0
Oral pain	3	0
Paraesthesia oral	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	10	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	1	0
<i>Stomatitis and ulceration</i>		
Lip ulceration	1	0
Mouth ulceration	7	0
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	4	0
Swollen tongue	3	0
Tongue blistering	1	0
Gastrointestinal disorders SOC TOTAL	254	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	30	0
Chronic fatigue syndrome	1	0
Fatigue	57	0
Malaise	94	0
<i>Complications associated with device NEC</i>		
Injury associated with device	3	0
<i>Death and sudden death</i>		
Death	3	3
Sudden death	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	61	0
<i>Feelings and sensations NEC</i>		
Chills	31	0
Feeling abnormal	12	0
Feeling cold	9	0
Feeling hot	19	0
Feeling of body temperature change	7	0
Sensation of foreign body	2	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	14	0
Disease prodromal stage	1	0
Exercise tolerance decreased	1	0
General physical health deterioration	2	0
Ill-defined disorder	1	0
Illness	5	0
Induration	3	0
Influenza like illness	31	0
Local reaction	16	0
Multiple organ dysfunction syndrome	2	0
Peripheral swelling	41	0
Swelling	28	0
Swelling face	5	0
<i>Inflammations</i>		
Inflammation	10	0
<i>Injection site reactions</i>		
Injection site bruising	5	0
Injection site discolouration	1	0
Injection site discomfort	1	0
Injection site dryness	1	0
Injection site eczema	2	0
Injection site erythema	42	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	1	0
Injection site induration	2	0
Injection site inflammation	2	0
Injection site injury	1	0

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General disorders General disorders cont'd		
Injection site irritation	1	0
Injection site mass	1	0
Injection site pain	21	0
Injection site paraesthesia	3	0
Injection site pruritus	18	0
Injection site rash	10	0
Injection site reaction	5	0
Injection site scab	1	0
Injection site swelling	30	0
Injection site urticaria	1	0
Injection site vesicles	6	0
Injection site warmth	10	0
Interactions		
Drug interaction	1	0
Oedema NEC		
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	2	0
Pain and discomfort NEC		
Axillary pain	4	0
Chest discomfort	5	0
Chest pain	18	0
Discomfort	4	0
Facial pain	11	0
Non-cardiac chest pain	1	0
Pain	136	0
Tenderness	7	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	19	0
Drug ineffective	4	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect incomplete	1	0
Therapeutic response unexpected	3	0
Therapy non-responder	1	0
Vaccination failure	46	0
Vaccination site reactions		
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	4	0
Vaccination site discomfort	2	0
Vaccination site dryness	1	0
Vaccination site erythema	29	0
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	4	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint inflammation	1	0
Vaccination site joint pain	3	0
Vaccination site joint swelling	1	0
Vaccination site mass	5	0
Vaccination site movement impairment	1	0
Vaccination site necrosis	2	0
Vaccination site nodule	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pain	29	0
Vaccination site pallor	1	0
Vaccination site papule	3	0
Vaccination site pruritus	8	0
Vaccination site rash	15	0
Vaccination site reaction	5	0
Vaccination site scar	1	0
Vaccination site swelling	26	0
Vaccination site ulcer	1	0
Vaccination site urticaria	2	0
Vaccination site vesicles	3	0
Vaccination site warmth	15	0
General disorders SOC TOTAL	1102	4

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	3	0
Hepatic disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	11	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	0
Immunisation reaction	2	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diverticulitis	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	10	0
Conjunctivitis bacterial	1	0
Folliculitis	2	0
Injection site cellulitis	2	0
Keratitis bacterial	1	0
Vaccination site cellulitis	2	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	5	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Labyrinthitis	3	0
Otitis media chronic	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
Eye infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	2	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster vaccine virus infection	1	0
Eczema herpeticum	1	0
Genital herpes simplex	2	0
Genital herpes zoster	1	0
Herpes ophthalmic	1	0
Herpes simplex	3	0
Herpes zoster	350	0
Herpes zoster cutaneous disseminated	6	0
Herpes zoster disseminated	2	1
Herpes zoster meningoencephalitis	1	0
Herpes zoster necrotising retinopathy	2	0
Herpes zoster oticus	7	0
Meningoencephalitis herpetic	2	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	13	0
Oral herpes	8	0
Oral herpes zoster	1	0
Varicella	35	0
Varicella post vaccine	1	0
Varicella zoster virus infection	6	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Infection reactivation	1	0
Infection susceptibility increased	1	0
Vaccine breakthrough infection	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	4	0
Secondary transmission	8	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	0
Pneumonia aspiration	1	0
<i>Mycoplasma infections</i>		
Mycoplasma infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	2	0
Dermatitis infected	2	0
Impetigo	1	0
Injection site pustule	1	0
Pustule	5	0
Rash pustular	2	0
Skin infection	1	0
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	4	0
Sinusitis	1	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	2	0
<i>Viral infections NEC</i>		
Encephalitis viral	1	0
Meningoencephalitis viral	1	0
Pleurisy viral	1	0
Post viral fatigue syndrome	1	0
Sweating fever	1	0
Vestibular neuronitis	1	0
Viral infection	2	0
Infections SOC TOTAL	542	1

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	11	0
Product use in unapproved indication	1	0
Product use issue	2	0
Vaccination error	5	0
Wrong technique in product usage process	3	0
<i>Nerve injuries NEC</i>		
Nerve injury	3	0
Nerve root injury	1	0
<i>Non-site specific injuries NEC</i>		
Eschar	1	0
Fall	3	0
Wound secretion	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	5	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Pathways and sources of exposure</i>		
Exposure via skin contact	1	0
<i>Product administration errors and issues</i>		
Contraindicated product administered	4	0
Extra dose administered	1	0
Inappropriate schedule of product administration	2	0
Incorrect dose administered	1	0
Incorrect route of product administration	9	0
Product administered at inappropriate site	5	0
Product administered to patient of inappropriate age	2	0
Product administration error	2	0
Product dose omission issue	1	0
Wrong product administered	4	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	1	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	2	0
<i>Skin injuries NEC</i>		
Contusion	6	0
Skin abrasion	2	0
Injuries SOC TOTAL	86	0

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Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	2	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	4	0
Heart rate irregular	2	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test abnormal	3	0
<i>Ophthalmic function diagnostic procedures</i>		
Intraocular pressure increased	2	0
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	9	0
Neurological examination abnormal	1	0
Weight decreased	2	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone decreased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	5	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	4	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	48	0

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Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	22	0
Hypophagia	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 2 diabetes mellitus	1	0
<i>Disorders of purine metabolism</i>		
Gout	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	4	0
Feeding disorder	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	35	0

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Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	4	0
Arthropathy	1	0
Polyarthritis	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	4	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	20	0
Scleroderma	1	0
<i>Extremity deformities</i>		
Hand deformity	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	97	0
Joint stiffness	4	0
Joint swelling	13	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
Polymyositis	1	0
<i>Muscle pains</i>		
Myalgia	67	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
Torticollis	2	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	19	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	3	0
Musculoskeletal stiffness	15	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	34	0
Limb discomfort	5	0
Musculoskeletal chest pain	7	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	5	0
Neck pain	16	0
Pain in extremity	113	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Rheumatoid arthropathies</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Rheumatoid arthritis	4	0
Soft tissue disorders NEC		
Groin pain	8	0
Spine and neck deformities		
Spinal stenosis	1	0
Spondyloarthropathies		
Arthritis reactive	2	0
Muscle & tissue disorders SOC TOTAL	473	0

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Earliest Reaction Date: 12-Feb-2011

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell small lymphocytic lymphomas</i>		
B-cell small lymphocytic lymphoma	1	0
<i>Lymphomas unspecified NEC</i>		
Central nervous system lymphoma	1	1
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Myelofibrosis	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Skin neoplasms benign</i>		
Leser-Trelat sign	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	1	0
Neoplasms SOC TOTAL	7	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
<i>Acute polyneuropathies</i>		
Acute polyneuropathy	1	0
Guillain-Barre syndrome	7	1
Miller Fisher syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
Cerebrovascular accident	4	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0
Balance disorder	12	0
Coordination abnormal	1	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	1
<i>Disturbances in consciousness NEC</i>		
Consciousness fluctuating	1	0
Depressed level of consciousness	2	0
Lethargy	23	0
Loss of consciousness	3	0
Somnolence	9	0
Syncope	12	0
<i>Dyskinesias and movement disorders NEC</i>		
Fine motor skill dysfunction	1	0
Hypokinesia	1	0
Movement disorder	3	0
<i>Eye movement disorders</i>		
Microvascular cranial nerve palsy	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	15	0
Facial paralysis	7	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Headache	139	0
Occipital neuralgia	1	0
Tension headache	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	5	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
Memory impairment	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Transient global amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	3	0
Mental impairment	1	0
Migraine headaches		
Migraine	3	0
Mononeuropathies		
Sciatic nerve neuropathy	1	0
Motor neurone diseases		
Motor neurone disease	1	1
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Hypotonia	1	0
Narcolepsy and hypersomnia		
Hypersomnia	3	0
Nervous system disorders NEC		
Central nervous system lesion	1	0
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	51	0
Dizziness postural	1	0
Head discomfort	2	0
Meningism	1	0
Presyncope	1	0
Unresponsive to stimuli	1	0
Paraesthesias and dysaesthesias		
Burning sensation	16	0
Formication	4	0
Hyperaesthesia	11	0
Hypoaesthesia	21	0
Paraesthesia	52	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Monoparesis	1	0
Partial complex seizures		
Dreamy state	1	0
Peripheral neuropathies NEC		
Neuralgic amyotrophy	3	0
Neuritis	1	0
Neuropathy peripheral	2	0
Seizures and seizure disorders NEC		
Seizure	6	0
Sensory abnormalities NEC		
Ageusia	1	0
Allodynia	2	0
Dysgeusia	5	0
Electric shock sensation	5	0
Neuralgia	49	0
Post herpetic neuralgia	25	0
Sensory disturbance	4	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Sensory loss	2	0
Speech and language abnormalities		
Dysarthria	5	0
Incoherent	1	0
Speech disorder	3	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	1	0
Tremor (excl congenital)		
Tremor	9	0
Trigeminal disorders		
Trigeminal neuralgia	5	0
Nervous system disorders SOC TOTAL	585	3

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Prolonged labour	1	0
Prolonged pregnancy	1	0
<i>Maternal complications of labour NEC</i>		
Labour complication	1	0
Pregnancy conditions SOC TOTAL	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	3	0
null SOC TOTAL	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
Staring	1	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	4	0
Nervousness	2	0
Stress	3	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Confusion and disorientation</i>		
Confusional state	12	0
Disorientation	5	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	4	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	7	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional disorder	1	0
Irritability	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
Hallucination, visual	2	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
Depressed mood	2	0
Feeling of despair	1	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	2	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Rapid eye movements sleep abnormal	1	0
<i>Perception disturbances NEC</i>		
Illusion	1	0
<i>Psychiatric symptoms NEC</i>		
Psychiatric symptom	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	4	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Thinking disturbances</i>		
Impaired reasoning	1	0
Psychiatric disorders SOC TOTAL	74	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Incontinence	1	0
Micturition disorder	1	0
Micturition urgency	1	0
Pollakiuria	6	0
Urinary incontinence	3	0
Urinary retention	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	1	0
<i>Renal disorders NEC</i>		
Single functional kidney	1	0
<i>Renal failure and impairment</i>		
Renal failure	2	0
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Chromaturia	3	0
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile erythema	1	0
Penile pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	1	0
Genital rash	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	16	0
Respiration abnormal	1	0
Tachypnoea	1	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Chronic obstructive pulmonary disease	1	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	13	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Pneumonitis	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
Nasal disorder	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
Sinus congestion	2	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
Lung consolidation	1	0
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	2	0
Tonsillar ulcer	1	0
<i>Pleural conditions NEC</i>		
Pleural adhesion	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Acute lung injury	1	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	2	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Catarrh	1	0
Dry throat	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Dysphonia	2	0
Increased upper airway secretion	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	11	0
Rhinorrhoea	5	0
Sinus pain	1	0
Sneezing	1	0
Throat irritation	1	0
Throat tightness	2	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	96	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	3	0
<i>Alopecias</i>		
Alopecia	1	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	4	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	11	0
Miliaria	1	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	63	0
Dermatitis bullous	3	0
Erythema multiforme	1	0
Pemphigoid	1	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	9	0
Macule	2	0
Pain of skin	14	0
Papule	18	0
Scab	10	0
Sensitive skin	7	0
Skin burning sensation	4	0
Skin discolouration	3	0
Skin discomfort	3	0
Skin disorder	1	0
Skin lesion	12	0
Skin reaction	8	0
Skin sensitisation	5	0
Skin texture abnormal	1	0
Skin warm	13	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	6	0
Dermatitis allergic	11	0
Eczema	8	0
Intertrigo	1	0
Skin irritation	14	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	85	0
<i>Exfoliative conditions</i>		
Skin exfoliation	7	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Panniculitides</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema nodosum	1	0
Papulosquamous conditions		
Lichen planus	2	0
Pityriasis rubra pilaris	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Solar dermatitis	1	0
Pruritus NEC		
Pruritus	128	0
Psoriatic conditions		
Psoriasis	3	0
Pustular psoriasis	1	0
Purpura and related conditions		
Petechiae	2	0
Purpura	6	0
Rashes, eruptions and exanthems NEC		
Rash	157	0
Rash erythematous	36	0
Rash macular	11	0
Rash maculo-papular	12	0
Rash morbilliform	1	0
Rash papular	21	0
Rash pruritic	44	0
Rash vesicular	141	0
Rosaceas		
Rosacea	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin ulcer	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin vasculitides		
Hypersensitivity vasculitis	4	0
Vasculitic rash	5	0
Skin vasomotor conditions		
Livedo reticularis	2	0
Urticarias		
Urticaria	37	0
Skin disorders SOC TOTAL	968	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	2	0
Loss of personal independence in daily activities	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	10	0
Impaired quality of life	1	0
Social circumstances SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	3	0
<i>Renal therapeutic procedures</i>		
Renal transplant	1	0
Surgical & medical procedures SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
Shock	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	4	0
Hot flush	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
<i>Varicose veins NEC</i>		
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	5	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	30	0
TOTAL REACTIONS FOR DRUG	4608	14
TOTAL REPORTS	1627	
TOTAL FATAL OUTCOME REPORTS		14