

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Data Lock Date: 18-Feb-2014 01:01:22
Earliest Reaction Date: 01-Nov-1999
MedDRA Version: MedDRA 16.1
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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Haematological disorders</i>		
Histiocytosis haematophagic	2	1
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	65	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	4	0
Pancytopenia	2	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Autoimmune thrombocytopenia	3	0
Idiopathic thrombocytopenic purpura	5	0
Thrombocytopenia	5	0
Blood disorders SOC TOTAL	90	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	79	0
Palpitations	5	0
<i>Heart failures NEC</i>		
Cardiac failure	2	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	36	0
Tachycardia	45	0
<i>Supraventricular arrhythmias</i>		
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	1
Cardio-respiratory arrest	2	0
Cardiac disorders SOC TOTAL	176	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Palate disorders congenital</i>		
Cleft palate	1	0
<i>Persistent foetal circulation disorders</i>		
Patent ductus arteriosus	1	0
Congenital disorders SOC TOTAL	3	0

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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	19	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness transitory	5	0
Hearing impaired	12	0
Hypoacusis	4	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	22	0
Vertigo	8	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
Ear disorders SOC TOTAL	76	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness transient	10	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival irritation	2	0
Conjunctivitis	3	0
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
Eyelid ptosis	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	11	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye pain	34	0
Eye swelling	18	0
Eyelid disorder	1	0
Periorbital oedema	9	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye inflammation	1	0
Eye irritation	5	0
Eye pruritus	2	0
Ocular hyperaemia	5	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	32	0
Gaze palsy	1	0
Strabismus	2	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	4	0
Photophobia	98	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Partial vision loss</i>		
Visual acuity reduced	3	0
<i>Pupil disorders</i>		
Mydriasis	14	0
Pupils unequal	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal degeneration	1	0
<i>Visual disorders NEC</i>		
Diplopia	16	0
Photopsia	11	0
Vision blurred	120	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual impairment	29	0
Eye disorders SOC TOTAL	452	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	263	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	4	0
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	198	0
Abdominal pain lower	1	0
Abdominal pain upper	158	0
Abdominal rigidity	1	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	20	0
Aphagia	1	0
Dysphagia	14	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Gingival pains</i>		
Gingival pain	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile spitting up	1	0
Nausea	1316	0
Regurgitation	2	0
Retching	5	0
Vomiting	1298	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
Haematochezia	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	5	0
Salivary hypersecretion	6	0
<i>Oral soft tissue pain and paraesthesia</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip pain	1	0
Odynophagia	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	4	0
Lip discolouration	1	0
Oral soft tissue swelling and oedema		
Gingival oedema	1	0
Gingival swelling	1	0
Lip swelling	24	0
Salivary gland enlargements		
Parotid gland enlargement	2	0
Salivary gland enlargement	2	0
Stomatitis and ulceration		
Aphthous stomatitis	1	0
Mouth ulceration	7	0
Tongue disorders		
Tongue ulceration	1	0
Tongue signs and symptoms		
Glossodynia	2	0
Protrusion tongue	1	0
Swollen tongue	11	0
Tongue discolouration	1	0
Tongue oedema	1	0
Tongue spasm	1	0
Gastrointestinal disorders SOC TOTAL	3392	0

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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Asthenia	94	0
Chronic fatigue syndrome	4	0
Fatigue	221	0
Malaise	1109	0
Sluggishness	1	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	1	1
Sudden death	3	3
Sudden infant death syndrome	10	10
<i>Febrile disorders</i>		
Hyperpyrexia	8	0
Pyrexia	1439	0
<i>Feelings and sensations NEC</i>		
Chills	120	0
Feeling abnormal	56	0
Feeling cold	62	0
Feeling hot	339	0
Feeling jittery	3	0
Feeling of body temperature change	53	0
Hangover	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Abasia	1	0
Gait disturbance	16	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crying	245	0
Developmental delay	3	0
Foaming at mouth	2	0
General symptom	1	0
Influenza like illness	118	0
Irritability	214	0
Local reaction	938	0
Local swelling	1096	0
Swelling	156	0
<i>Inflammations</i>		
Inflammation	222	0
Soft tissue inflammation	1	0
<i>Infusion site reactions</i>		
Infusion site erythema	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site bruising	1	0
Injection site dermatitis	1	0
Injection site discharge	1	0
Injection site discolouration	1	0
Injection site erythema	19	0
Injection site fibrosis	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site granuloma	1	0
Injection site haemorrhage	5	0
Injection site hypersensitivity	1	0
Injection site induration	2	0
Injection site inflammation	450	0
Injection site mass	19	0
Injection site pain	108	0
Injection site rash	60	0
Injection site reaction	835	0
Injection site scar	1	0
Injection site swelling	16	0
Injection site ulcer	1	0
Injection site urticaria	1	0
Injection site vesicles	2	0
Mass conditions NEC		
Cyst	1	0
Mass	3	0
Oedema NEC		
Face oedema	7	0
Generalised oedema	3	0
Localised oedema	2	0
Oedema	8	0
Oedema peripheral	109	0
Pain and discomfort NEC		
Axillary pain	10	0
Chest discomfort	35	0
Chest pain	39	0
Discomfort	1	0
Facial pain	1	0
Pain	155	0
Tenderness	38	0
Therapeutic and nontherapeutic responses		
Drug ineffective	7	0
Vaccination site reactions		
Vaccination site erythema	1	0
Vaccination site induration	1	0
Vaccination site pain	4	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	8498	14

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	3	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	49	0
Serum sickness-like reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
Milk allergy	1	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	60	0
Anaphylactic shock	9	0
Anaphylactoid reaction	7	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immunisation reaction	2	0
Immune system disorders SOC TOTAL	131	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	4	0
<i>Arenaviral infections</i>		
Choriomeningitis lymphocytic	1	0
<i>Bacterial infections NEC</i>		
Bacterial infection	3	0
Cellulitis	59	0
Injection site cellulitis	20	0
Meningitis bacterial	3	1
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Candida infections</i>		
Oral candidiasis	3	0
Vulvovaginal candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Meningitis	17	1
Meningitis aseptic	2	0
<i>Coxsackie viral infections</i>		
Epidemic pleurodynia	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Parotitis	1	0
<i>Ear infections</i>		
Ear infection	4	0
Otitis media	5	0
<i>Eye and eyelid infections</i>		
Conjunctivitis infective	1	0
Hordeolum	1	0
<i>Haemophilus infections</i>		
Epiglottitis haemophilus	1	0
Haemophilus infection	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Exanthema subitum	1	0
Herpes zoster	10	0
Oral herpes	3	0
Varicella	4	0
<i>Infections NEC</i>		
Abscess	4	0
Infection	6	0
Injection site abscess	12	0
Injection site infection	2	0
Localised infection	4	0
Vaccination site abscess	2	0
Vaccination site infection	1	0
Wound infection	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchopneumonia	2	1
Lobar pneumonia	1	0
Lower respiratory tract infection	7	0
Pneumonia	1	1

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Neisseria infections</i>		
Meningitis meningococcal	32	1
Meningococcal bacteraemia	16	2
Meningococcal infection	35	0
Meningococcal sepsis	31	3
<i>Parainfluenzae viral infections</i>		
Croup infectious	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	1
<i>Salmonella infections</i>		
Salmonellosis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	6	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	2	0
Impetigo	3	0
Rash pustular	4	0
Skin infection	2	0
<i>Staphylococcal infections</i>		
Eye infection staphylococcal	1	0
<i>Streptococcal infections</i>		
Pneumococcal infection	2	0
Pneumococcal sepsis	1	1
<i>Tuberculous infections</i>		
Erythema induratum	51	0
<i>Upper respiratory tract infections</i>		
Laryngitis	2	0
Nasal vestibulitis	1	0
Nasopharyngitis	77	0
Pharyngitis	12	0
Rhinitis	8	0
Sinusitis	1	0
Tonsillitis	9	0
Upper respiratory tract infection	10	0
<i>Urinary tract infections</i>		
Urinary tract infection	2	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Bronchiolitis	5	1
Encephalitis viral	3	0
Kaposi's varicelliform eruption	1	0
Meningitis viral	3	0
Post viral fatigue syndrome	8	0
Viral infection	10	0
Viral rash	3	0
Viral upper respiratory tract infection	2	0
Infections SOC TOTAL	540	13

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Subdural haemorrhage	1	0
<i>Maladministrations</i>		
Drug administration error	1	0
Incorrect dose administered	1	0
Incorrect route of drug administration	1	0
Wrong drug administered	2	0
<i>Non-site specific injuries NEC</i>		
Electric shock	1	0
Fall	22	0
Wound secretion	1	0
<i>Overdoses</i>		
Overdose	4	0
<i>Skin injuries NEC</i>		
Contusion	29	0
Scratch	1	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Vaccination failure	124	0
Injuries SOC TOTAL	191	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	12	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	3	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	2	0
Heart rate decreased	25	0
Heart rate increased	42	0
Heart rate irregular	14	0
Pulse abnormal	8	0
Pulse absent	3	0
Pulse pressure decreased	48	0
<i>Immunology analyses NEC</i>		
Tryptase increased	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	1	0
<i>Neurologic diagnostic procedures</i>		
Electroencephalogram abnormal	1	0
Romberg test positive	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	36	0
Body temperature decreased	3	0
Body temperature increased	149	0
Respiratory rate decreased	3	0
Respiratory rate increased	5	0
Weight decreased	5	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
Platelet count increased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	3	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	2	0
<i>Renal function analyses</i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	12	0
Blood pressure increased	5	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
White blood cell count increased	4	0
Investigations SOC TOTAL	399	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	93	0
Hyperphagia	1	0
Hypophagia	1	0
<i>Calcium metabolism disorders</i>		
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	2	0
<i>General nutritional disorders NEC</i>		
Failure to thrive	1	0
Feeding disorder	6	0
Feeding disorder neonatal	4	0
Feeding disorder of infancy or early childhood	36	0
Weight gain poor	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	5	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	7	0
Metabolic disorders SOC TOTAL	166	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	9	0
Arthritis reactive	2	0
Arthropathy	2	0
Polyarthritis	2	0
Seronegative arthritis	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	77	0
Joint stiffness	9	0
Joint swelling	16	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	91	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	12	0
Muscle spasms	18	0
Muscle tightness	2	0
Muscle twitching	108	0
<i>Muscle tone abnormalities</i>		
Floppy infant	7	0
Muscle rigidity	73	0
Torticollis	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	39	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	63	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	12	0
Neck pain	131	0
Pain in extremity	637	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	228	0
Sensation of heaviness	28	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<i>Synovial disorders</i>		
Synovitis	2	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	1584	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
<i>Non-small cell neoplasms malignant of the respiratory tract cell type specified</i>		
Lung adenocarcinoma stage IV	1	1
<i>Skin neoplasms benign</i>		
Haemangioma of skin	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	12	0
Neoplasms SOC TOTAL	17	1

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

Data Lock Date: 18-Feb-2014 01:01:22
MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	10	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	4	0
Balance disorder	18	0
Coordination abnormal	4	0
Developmental coordination disorder	1	0
Dysstasia	4	0
Nystagmus	2	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Developmental disorders cognitive</i>		
Autism	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	11	0
Lethargy	173	0
Loss of consciousness	85	0
Somnolence	275	0
Stupor	1	0
Syncope	1302	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	50	0
Hypokinesia	1	0
Movement disorder	3	0
Psychomotor hyperactivity	11	0
<i>Dystonias</i>		
Dystonia	1	0
Opisthotonus	5	0
<i>Encephalitis NEC</i>		
Encephalitis	7	1
Encephalomyelitis	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	4	0
<i>Facial cranial nerve disorders</i>		
Facial paresis	1	0
VIIth nerve paralysis	12	0
<i>Generalised tonic-clonic seizures</i>		
Grand mal convulsion	44	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	2645	0
Tension headache	1	0
<i>Increased intracranial pressure disorders</i>		
Benign intracranial hypertension	1	0
Brain oedema	1	1
Intracranial pressure increased	2	0
<i>Memory loss (excl dementia)</i>		

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014

Data Lock Date: 18-Feb-2014 01:01:22

Earliest Reaction Date: 01-Nov-1999

MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	9	0
Migraine headaches		
Migraine	19	0
Migraine with aura	1	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Muscle tone abnormal		
Hypotonia	93	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Narcolepsy and hypersomnia		
Hypersomnia	2	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Motor dysfunction	1	0
Nervous system disorder	2	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	2216	0
Dizziness postural	2	0
Drooling	1	0
Fontanelle bulging	5	0
Grimacing	1	0
Head discomfort	1	0
Inability to crawl	1	0
Meningism	16	0
Presyncope	81	0
Slow response to stimuli	3	0
Unresponsive to stimuli	39	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	4	0
Muscle spasticity	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Parosmia	1	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning sensation	4	0
Hyperaesthesia	14	0
Paraesthesia	158	0
Paraesthesia mucosal	1	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Monoparesis	1	0
Paralysis	1	0
Partial complex seizures		
Complex partial seizures	2	0
Peripheral neuropathies NEC		

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsion	183	1
Epilepsy	42	0
Epileptic aura	1	0
Febrile convulsion	36	0
Frontal lobe epilepsy	1	0
Hypoglycaemic seizure	1	0
Infantile spasms	2	0
Myoclonic epilepsy	1	0
Partial seizures	6	0
Seizure anoxic	11	0
Seizure like phenomena	1	0
Status epilepticus	2	0
Sensory abnormalities NEC		
Complex regional pain syndrome	1	0
Dysgeusia	8	0
Hypoaesthesia	138	0
Neuralgia	1	0
Sensory disturbance	3	0
Sensory loss	5	0
Sleep disturbances NEC		
Poor quality sleep	8	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Aphonia	1	0
Dysarthria	6	0
Speech disorder	4	0
Speech disorder developmental	2	0
Tremor (excl congenital)		
Tremor	122	0
Nervous system disorders SOC TOTAL	7970	3

Case Series Drug Analysis Print

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Report Run Date: 20-Feb-2014
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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

Data Lock Date: 18-Feb-2014 01:01:22
MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	21	0
Breath holding	8	0
Staring	4	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
<i>Anxiety symptoms</i>		
Agitation	10	0
Agitation neonatal	1	0
Anxiety	16	0
Nervousness	52	0
Tension	3	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit/hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	10	0
Paranoia	1	0
Personality change	4	0
<i>Communications disorders</i>		
Expressive language disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	10	0
Disorientation	20	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	15	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	11	0
<i>Eating disorders NEC</i>		
Eating disorder	6	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	18	0
Mood altered	8	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Nosophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	2	0
<i>Increased physical activity levels</i>		
Restlessness	17	0
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	4	0
Tearfulness	12	0
<i>Mood disorders NEC</i>		
Listless	14	0
<i>Narcolepsy and associated conditions</i>		

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep attacks	1	0
<i>Panic attacks and disorders</i>		
Panic attack	5	0
Panic reaction	4	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
Nightmare	2	0
Sleep talking	1	0
Sleep terror	3	0
<i>Perception disturbances</i>		
Hallucination	18	0
Hallucinations, mixed	2	0
<i>Personality disorders with dramatic behaviour (Cluster B)</i>		
Histrionic personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	24	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0
Screaming	140	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicide attempt	1	0
<i>Tic disorders</i>		
Tic	2	0
Psychiatric disorders SOC TOTAL	489	0

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Enuresis	1	0
Incontinence	6	0
Urinary incontinence	17	0
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis acute	1	0
Glomerulonephritis membranoproliferative	1	0
IgA nephropathy	1	0
Nephrotic syndrome	3	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal failure and impairment</i>		
Renal failure chronic	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Haematuria	7	0
Proteinuria	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal colic	1	0
Renal & urinary disorders SOC TOTAL	47	0

Case Series Drug Analysis Print

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Report Run Date: 20-Feb-2014
 Earliest Reaction Date: 01-Nov-1999

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 MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Polymenorrhoea	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Oedema genital	2	0
<i>Testicular and epididymal disorders NEC</i>		
Epididymal tenderness	1	0
Testicular pain	1	0
Reproductive & breast disorders SOC TOTAL	9	0

Case Series Drug Analysis Print

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Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

Data Lock Date: 18-Feb-2014 01:01:22
MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	18	0
Apnoeic attack	7	0
Dyspnoea	64	0
Grunting	2	0
Hyperventilation	38	0
Hypopnoea	10	0
Respiratory arrest	13	1
Respiratory distress	5	0
Tachypnoea	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	17	0
Bronchospasm	11	0
Wheezing	31	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	2	0
Hypoxia	1	1
<i>Coughing and associated symptoms</i>		
Cough	57	0
Productive cough	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngospasm	1	0
Stridor	8	0
<i>Lower respiratory tract signs and symptoms</i>		
Pleuritic pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	16	0
<i>Neonatal hypoxic conditions</i>		
Apnoea neonatal	5	0
Cyanosis neonatal	1	0
Neonatal respiratory distress syndrome	1	0
<i>Newborn respiratory disorders NEC</i>		
Respiratory disorder neonatal	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal oedema	9	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	1
Respiratory disorder	2	0
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	2	0
Dry throat	3	0
Dysphonia	2	0
Nasal discomfort	1	0
Oropharyngeal pain	153	0
Rhinorrhoea	15	0

Case Series Drug Analysis Print

Name: Men C

Report Run Date: 20-Feb-2014
Earliest Reaction Date: 01-Nov-1999

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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sneezing	3	0
Throat irritation	7	0
Throat tightness	31	0
Yawning	2	0
Respiratory disorders SOC TOTAL	556	4

Case Series Drug Analysis Print

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Report Run Date: 20-Feb-2014
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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Dermatitis acneiform	1	0
Alopecias		
Alopecia	4	0
Angioedemas		
Angioedema	15	0
Swelling face	47	0
Apocrine and eccrine gland disorders		
Cold sweat	282	0
Hyperhidrosis	267	0
Miliaria	5	0
Night sweats	1	0
Bullous conditions		
Blister	27	0
Dermatitis bullous	5	0
Erythema multiforme	32	0
Pemphigoid	1	0
Stevens-Johnson syndrome	2	0
Dermal and epidermal conditions NEC		
Dry skin	8	0
Macule	3	0
Pain of skin	25	0
Papule	1	0
Skin burning sensation	2	0
Skin discolouration	30	0
Skin discomfort	1	0
Skin disorder	3	0
Skin induration	61	0
Skin lesion	8	0
Skin odour abnormal	1	0
Skin reaction	55	0
Skin tightness	2	0
Skin warm	5	0
Dermatitis and eczema		
Dermatitis	2	0
Dermatitis allergic	15	0
Dermatitis atopic	1	0
Eczema	39	0
Eczema infantile	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	6	0
Erythemas		
Erythema	853	0
Generalised erythema	5	0
Palmar erythema	1	0
Rash erythematous	105	0
Exfoliative conditions		
Dermatitis exfoliative	1	0
Skin exfoliation	5	0
Panniculitides		
Erythema nodosum	2	0
Papulosquamous conditions		
Erythema annulare	1	0

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Report Run Date: 20-Feb-2014
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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pityriasis rosea	2	0
Rash papular	41	0
Photosensitivity and photodermatosi		
Photosensitivity reaction	2	0
Pilar disorders NEC		
Hair growth abnormal	2	0
Pruritus NEC		
Pruritus	173	0
Pruritus generalised	6	0
Rash pruritic	55	0
Psoriatic conditions		
Guttate psoriasis	2	0
Psoriasis	3	0
Purpura and related conditions		
Henoch-Schonlein purpura	10	0
Petechiae	187	0
Purpura	115	0
Pustular conditions		
Rash follicular	1	0
Rashes, eruptions and exanthe		
Rash	566	0
Rash generalised	94	0
Rash macular	220	0
Rash maculo-papular	73	0
Rash morbilliform	9	0
Rash rubelliform	3	0
Rash vesicular	12	0
Skin and subcutaneous conditions		
Skin mass	2	0
Skin and subcutaneous tissue ulcerations		
Skin ulcer	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin vasculitides		
Capillaritis	1	0
Leukocytoclastic vasculitis	1	0
Vasculitic rash	6	0
Skin vasomotor conditions		
Livedo reticularis	25	0
Urticarias		
Urticaria	363	0
Urticaria chronic	1	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	3910	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	4	0
Social circumstances SOC TOTAL	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Middle ear therapeutic procedures</i>		
Ear tube insertion	1	0
<i>Tonsillar therapeutic procedures</i>		
Adenoidectomy	1	0
Tonsillectomy	1	0
Surgical & medical procedures SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: Men C

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MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial inflammations</i>		
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	76	0
Peripheral circulatory failure	3	0
Shock	10	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	2	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	174	0
Hot flush	7	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	39	0
Peripheral ischaemia	2	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	2	0
Vasoconstriction	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1052	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	31	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	5	0
Vascular disorders SOC TOTAL	1415	0
TOTAL REACTIONS FOR DRUG	30130	37
TOTAL REPORTS	14480	
TOTAL FATAL OUTCOME REPORTS		37