

Case Series Drug Analysis Print

Name: FOI 24/273 Fostair Product Analysis Print (PAP)

Report Run Date: 20-Mar-2024

Data Lock Date: 19-Mar-2024 18:30:03

Earliest Reaction Date: 02-Jun-1998

MedDRA Version: MedDRA 26.1

FOI 24/273 Fostair All UK spontaneous suspected Adverse Drug Reaction
Product Analysis Print (ADR) reports associated with Fostair up to and
(PAP): including 19/03/2024

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Reaction Name	Total	Fatal
Blood disorders		
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
Blood disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	157	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	5	0
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	5	0
Extrasystoles	4	0
Tachycardia	14	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	6	0
Atrial flutter	1	0
Sinus tachycardia	2	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardio-respiratory arrest	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	201	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear inflammation	1	0
Ear pain	3	0
<i>Hearing losses</i>		
Deafness	2	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	6	0
Vertigo	5	0
Ear disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hyperfunctions</i>		
Cushing's syndrome	1	0
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	1	0
Adrenal suppression	1	0
Steroid withdrawal syndrome	1	0
<i>Thyroid hyperfunction disorders</i>		
Graves' disease	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
Eyelid ptosis	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Lacrimation disorders</i>		
Dry eye	3	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	3	0
<i>Ocular disorders NEC</i>		
Eye pain	4	0
Eye swelling	7	0
Eyelid disorder	1	0
Ocular discomfort	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye pruritus	2	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal detachment	1	0
<i>Retinopathies NEC</i>		
Central serous chorioretinopathy	4	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Photopsia	1	0
Vision blurred	16	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	2	0
Visual impairment	2	0
Eye disorders SOC TOTAL	59	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis acute	1	0
<i>Benign oral cavity neoplasms</i>		
Tongue cyst	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	19	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	11	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain upper	9	0
Abdominal rigidity	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	12	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Dysphagia	12	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	48	0
Vomiting	14	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal obstruction	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	21	0
Saliva altered	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	2	0
Lip blister	5	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	3	0
Oral blood blister	2	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	6	0
Lip pain	1	0
Lip pruritus	1	0
Oral discomfort	5	0
Oral mucosal blistering	3	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Oral mucosal erythema	1	0
Oral mucosal exfoliation	1	0
Oral pain	20	0
Oral pruritus	2	0
Paraesthesia oral	9	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	14	0
Mouth swelling	2	0
Palatal oedema	3	0
Stomatitis and ulceration		
Mouth ulceration	17	0
Stomatitis	6	0
Tongue disorders		
Plicated tongue	2	0
Tongue disorder	1	0
Tongue haemorrhage	1	0
Tongue ulceration	1	0
Tongue signs and symptoms		
Glossodynia	12	0
Swollen tongue	23	0
Tongue blistering	2	0
Tongue discolouration	2	0
Tongue discomfort	7	0
Tongue dry	1	0
Tongue eruption	1	0
Tongue erythema	1	0
Tongue exfoliation	1	0
Gastrointestinal disorders SOC TOTAL	342	0

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General disorders		
<i>Application and instillation site reactions</i>		
Instillation site foreign body sensation	1	0
<i>Asthenic conditions</i>		
Asthenia	15	0
Fatigue	18	0
Malaise	43	0
<i>Death and sudden death</i>		
Death	1	1
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	5	0
<i>Feelings and sensations NEC</i>		
Chills	7	0
Feeling abnormal	8	0
Feeling cold	2	0
Feeling drunk	5	0
Feeling hot	4	0
Feeling jittery	9	0
Hangover	1	0
Sensation of foreign body	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	18	0
Crying	3	0
Disease progression	1	0
Exercise tolerance decreased	2	0
Ill-defined disorder	5	0
Illness	4	0
Influenza like illness	7	0
Peripheral swelling	19	0
Secretion discharge	2	0
Swelling	6	0
Swelling face	21	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Inflammations</i>		
Inflammation	4	0
<i>Injection site reactions</i>		
Injection site pain	2	0
<i>Interactions</i>		
Alcohol interaction	1	0
Drug interaction	3	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Mucosal findings abnormal</i>		
Mucosal inflammation	1	0
<i>Oedema NEC</i>		
Face oedema	2	0
Oedema peripheral	3	0
<i>Pain and discomfort NEC</i>		

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General disorders General disorders cont'd		
Chest discomfort	67	0
Chest pain	35	0
Non-cardiac chest pain	2	0
Pain	10	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	4	0
Adverse event	4	0
Drug ineffective	46	0
Drug intolerance	1	0
Idiosyncratic drug reaction	1	0
Therapeutic product effect decreased	5	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	1	0
Treatment noncompliance	14	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	423	2

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to animal	2	0
Allergy to arthropod bite	1	0
Hypersensitivity	13	0
Mite allergy	2	0
Mycotic allergy	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
Anaphylactic shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	4	0
<i>Immunodeficiency disorders NEC</i>		
Immunosuppression	1	0
Immune system disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Candida infections</i>		
Candida infection	1	0
Oesophageal candidiasis	2	0
Oral candidiasis	32	0
Oropharyngeal candidiasis	1	0
Skin candida	2	0
Vulvovaginal candidiasis	3	0
<i>Coronavirus infections</i>		
COVID-19	13	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingival abscess	1	0
Gingivitis	2	0
<i>Ear infections</i>		
Ear infection	1	0
Otosalpingitis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	2	0
Severe asthma with fungal sensitisation	1	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	14	0
Pneumonia	5	0
Pneumonia aspiration	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
<i>Trematode infections</i>		
Paragonimiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	3	0
Nasopharyngitis	1	0
Pharyngitis	1	0
Rhinitis	3	0
Sinusitis	3	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Infections SOC TOTAL	103	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	2	0
Maternal exposure during pregnancy	7	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Intentional product misuses</i>		
Intentional device misuse	3	0
Intentional product misuse	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	1	0
Medication error	10	0
Product use in unapproved indication	2	0
Product use issue	6	0
Wrong technique in product usage process	20	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
<i>Off label uses</i>		
Off label use	28	0
<i>Overdoses NEC</i>		
Overdose	5	0
Prescribed overdose	5	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Drug administered in wrong device	13	0
Drug dose omission by device	1	0
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	2	0
Incorrect dose administered by device	9	0
Incorrect dose administered by product	1	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product dose omission issue	31	0
<i>Product dispensing errors and issues</i>		
Drug dispensed to wrong patient	1	0
Product dispensing error	6	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	2	0
Product prescribing error	1	0
Product prescribing issue	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	4	0
<i>Product transcribing errors and communication issues</i>		
Product communication issue	1	0
<i>Skin injuries NEC</i>		
Contusion	16	0
<i>Skull fractures, facial bone fractures and dislocations</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skull fracture	1	0
Spinal fractures and dislocations		
Lumbar vertebral fracture	1	0
Thermal burns		
Burn oral cavity	1	0
Injuries SOC TOTAL	197	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol free urine increased	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	2	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	2	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio abnormal	1	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	4	0
Electrocardiogram abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	1	0
Heart rate increased	24	0
Heart rate irregular	4	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase decreased	1	0
Alanine aminotransferase increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	1	0
Product residue present	2	0
Respiratory rate decreased	2	0
Weight increased	4	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
FEV1/FVC ratio decreased	1	0
Inspiratory capacity decreased	1	0
Peak expiratory flow rate decreased	3	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	2	0
<i>Thyroid analyses</i>		
Thyroid function test abnormal	1	0
<i>Toxicology laboratory analyses</i>		
Drug screen false positive	1	0
<i>Urinalysis NEC</i>		
Blood urine present	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	3	0
<i>Virus identification and serology</i>		
SARS-CoV-2 test negative	1	0
Investigations SOC TOTAL	68	0

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Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	3	0
Food craving	1	0
Increased appetite	1	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	1	0
Type 2 diabetes mellitus	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	3	0
Food aversion	1	0
Weight loss poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	1	0
Spinal pain	1	0
<i>Connective tissue disorders NEC</i>		
Sjogren's syndrome	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	10	0
Joint swelling	4	0
<i>Metabolic bone disorders</i>		
Osteoporosis	3	0
<i>Muscle pains</i>		
Myalgia	27	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	138	0
Muscle tightness	2	0
Muscle twitching	4	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	11	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	12	0
Flank pain	1	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	2	0
Pain in extremity	14	0
Muscle & tissue disorders SOC TOTAL	242	0

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Neoplasms		
<i>Adrenal neoplasms benign</i>		
Adrenal adenoma	1	0
<i>Aural neoplasms benign</i>		
Cholesteatoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Neoplasms SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	2	0
<i>Central nervous system vascular disorders NEC</i>		
Carotid artery stenosis	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	6	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	9	0
Loss of consciousness	3	0
Somnolence	3	0
Syncope	3	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<i>Headaches NEC</i>		
Headache	115	0
Tension headache	2	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	6	0
Retinal migraine	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system cysts and polyps</i>		
Cerebral cyst	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia homonymous	1	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	2	0
Dizziness	104	0
Dizziness postural	5	0
Head discomfort	2	0
Presyncope	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	3	0
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	9	0
Burning sensation mucosal	1	0
Formication	1	0
Hyperaesthesia	2	0
Hypoaesthesia	2	0
Paraesthesia	21	0
<i>Seizures and seizure disorders NEC</i>		
Post-traumatic epilepsy	1	0
Seizure	3	0

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Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Sensory abnormalities NEC</i>		
Ageusia	5	0
Dysgeusia	10	0
Hypogeusia	1	0
Neuralgia	1	0
Restless legs syndrome	3	0
Sensory disturbance	1	0
Taste disorder	12	0
<i>Speech and language abnormalities</i>		
Incoherent	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
<i>Tremor (excl congenital)</i>		
Action tremor	1	0
Essential tremor	4	0
Head titubation	1	0
Resting tremor	1	0
Tremor	233	0
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	1	0
Nervous system disorders SOC TOTAL	598	0

Case Series Drug Analysis Print

Name: FOI 24/273 Fostair Product Analysis Print (PAP)

Report Run Date: 20-Mar-2024

Data Lock Date: 19-Mar-2024 18:30:03

Earliest Reaction Date: 02-Jun-1998

MedDRA Version: MedDRA 26.1

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
Pregnancy conditions SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: FOI 24/273 Fostair Product Analysis Print (PAP)

Report Run Date: 20-Mar-2024
 Earliest Reaction Date: 02-Jun-1998

Data Lock Date: 19-Mar-2024 18:30:03
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device delivery system issue	3	0
Device failure	2	0
Device issue	31	0
<i>Device malfunction events NEC</i>		
Device malfunction	48	0
Device occlusion	1	0
<i>Device physical property and chemical issues</i>		
Device defective	1	0
<i>Product contamination and sterility issues</i>		
Product cleaning inadequate	1	0
<i>Product physical issues</i>		
Product taste abnormal	3	0
<i>Product quality issues NEC</i>		
Drug delivery system issue	1	0
Product complaint	9	0
Product quality issue	5	0
Product substitution issue	6	0
Product tampering	1	0
SOB TOTAL	112	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
<i>Anxiety symptoms</i>		
Agitation	8	0
Anxiety	46	0
Nervousness	8	0
Stress	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	7	0
Disorientation	4	0
<i>Depressive disorders</i>		
Depression	7	0
Depression suicidal	1	0
Major depression	1	0
<i>Dissociative states</i>		
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	28	0
Middle insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	5	0
<i>Emotional and mood disturbances NEC</i>		
Anger	4	0
Emotional disorder	3	0
Emotional distress	2	0
Irritability	4	0
Mood altered	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	7	0
Hallucination, visual	1	0
<i>Increased physical activity levels</i>		
Restlessness	13	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychological symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	6	0
Tearfulness	2	0
<i>Panic attacks and disorders</i>		
Panic attack	4	0
Panic disorder	1	0
Panic reaction	2	0
<i>Parasomnias</i>		
Abnormal dreams	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Nightmare	3	0
Sleep terror	1	0
Sexual desire disorders		
Loss of libido	2	0
Sleep disorders NEC		
Sleep disorder	10	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Stereotypies and automatisms		
Bruxism	1	0
Suicidal and self-injurious behaviour		
Self-injurious ideation	1	0
Suicidal ideation	3	0
Thinking disturbances		
Tachyphrenia	1	0
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	213	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	1	0
Dysuria	1	0
Pollakiuria	3	0
Urinary retention	2	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Renal failure and impairment</i>		
Renal failure	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	10	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital swelling	1	0
Reproductive & breast disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	123	1
Dyspnoea at rest	1	0
Dyspnoea exertional	6	0
Hyperventilation	2	0
Hypopnoea	1	0
Respiration abnormal	1	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	83	0
Bronchospasm	15	0
Bronchospasm paradoxical	4	0
Chronic obstructive pulmonary disease	7	0
Wheezing	36	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	102	0
Haemoptysis	4	0
Productive cough	18	0
Sputum discoloured	4	0
Sputum increased	1	0
Sputum retention	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Vocal cord atrophy	1	0
Vocal cord dysfunction	1	0
Vocal cord thickening	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary haemorrhage	1	0
Pulmonary pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
Nasal inflammation	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	12	0
Nasal cyst	1	0
Nasal dryness	1	0
<i>Newborn respiratory disorders NEC</i>		
Bronchopulmonary dysplasia	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
Sinus congestion	2	0
Sinus disorder	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal spasm	1	0
Pharyngeal erythema	2	0
Pharyngeal inflammation	1	0
Pharyngeal swelling	13	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	1
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Respiratory tract congestion	3	0
Respiratory tract irritation	2	0
Respiratory tract oedema	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	8	0
Catarrh	4	0
Choking	1	0
Choking sensation	1	0
Dry throat	8	0
Dysphonia	35	0
Increased viscosity of upper respiratory secretion	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	51	0
Rhinorrhoea	5	0
Sneezing	1	0
Throat clearing	1	0
Throat irritation	26	0
Throat tightness	12	0
Respiratory disorders SOC TOTAL	630	3

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
<i>Alopecias</i>		
Alopecia	4	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	6	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	20	0
Night sweats	4	0
<i>Bullous conditions</i>		
Blister	4	0
Blood blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	7	0
Pain of skin	3	0
Papule	3	0
Skin burning sensation	2	0
Skin discolouration	1	0
Skin lesion	1	0
Skin reaction	2	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	7	0
Eczema	4	0
Eczema weeping	1	0
Intertrigo	1	0
Perioral dermatitis	3	0
<i>Erythemas</i>		
Erythema	21	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	5	0
<i>Pilar disorders NEC</i>		
Hair colour changes	1	0
Hair growth abnormal	1	0
<i>Pruritus NEC</i>		
Pruritus	31	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
Purpura	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	55	0
Rash erythematous	5	0
Rash macular	7	0
Rash papular	2	0
Rash pruritic	5	0
Rash vesicular	3	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	6	0
<i>Urticarias</i>		
Urticaria	11	0
Skin disorders SOC TOTAL	237	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Impaired driving ability	1	0
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Therapeutic procedures NEC</i>		
Hospitalisation	1	0
Product substitution	1	0
Therapy change	1	0
Surgical & medical procedures SOC TOTAL	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	2	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	1
<i>Peripheral vascular disorders NEC</i>		
Flushing	8	0
Hot flush	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	7	0
Vascular disorders SOC TOTAL	23	1
TOTAL REACTIONS FOR DRUG	3558	6
TOTAL REPORTS	1524	
TOTAL FATAL OUTCOME REPORTS		6