

Case Series Drug Analysis Print

Name: FOI 23/461 Botulinum Toxin Drug Analysis Print

Report Run Date: 28-Jul-2023

Data Lock Date: 27-Jul-2023 18:30:03

Earliest Reaction Date: 04-Sep-1998

MedDRA Version: MedDRA 26.0

FOI 23/461 Botulinum Toxin Drug Analysis Print: All UK spontaneous Adverse Drug Reaction (ADR) reports associated with botulinum toxin used for aesthetic purposes up to and including 27/07/2023.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	4	0
Lymphatic disorder	1	0
Lymphatic obstruction	1	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block first degree	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	13	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	3	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	4	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
Congenital disorders SOC TOTAL	1	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	3	0
Ear swelling	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness neurosensory	1	0
<i>Hyperacusia</i>		
Hyperacusis	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	9	0
Vertigo	5	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
Ear disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Vitreous haemorrhage	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	3	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
Eyelid ptosis	28	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Uveitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	15	0
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	3	0
Eyelid irritation	1	0
Eyelid oedema	1	0
Swelling of eyelid	5	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid thickening	2	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	2	0
Eye disorder	2	0
Eye oedema	2	0
Eye pain	10	0
Eye swelling	19	0
Eyelid disorder	3	0
Eyelids pruritus	1	0
Ocular discomfort	4	0
Periorbital oedema	3	0
Periorbital swelling	16	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	3	0
Eye pruritus	4	0
Ocular hyperaemia	3	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
Ocular myasthenia	1	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	3	0
Asthenopia	8	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Foreign body sensation in eyes	1	0
Photophobia	5	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
Orbital swelling	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Visual disorders NEC</i>		
Diplopia	10	0
Photopsia	1	0
Vision blurred	25	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	2	0
Blindness transient	2	0
Visual impairment	10	0
Eye disorders SOC TOTAL	217	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Crohn's disease	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	9	0
<i>Dyspeptic signs and symptoms</i>		
Eructation	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Anal incontinence	1	0
Dysphagia	21	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	29	0
Vomiting	7	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	13	0
<i>Oral soft tissue disorders NEC</i>		
Lip disorder	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	4	0
Lip discolouration	1	0
Lip pain	1	0
Oral discomfort	1	0
Oral pain	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	5	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	114	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site necrosis	1	0
Puncture site haemorrhage	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	10	0
Chronic fatigue syndrome	1	0
Fatigue	23	0
Malaise	32	0
<i>Febrile disorders</i>		
Pyrexia	6	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	10	0
Feeling cold	3	0
Feeling hot	2	0
Hangover	2	0
Temperature intolerance	1	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	5	0
Crepitations	1	0
Deformity	1	0
Illness	8	0
Induration	1	0
Influenza like illness	18	0
Peripheral swelling	1	0
Swelling	8	0
Swelling face	19	0
Unevaluable event	2	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Inflammations</i>		
Inflammation	5	0
Papillitis	1	0
<i>Injection site reactions</i>		
Injection site alopecia	1	0
Injection site bruising	9	0
Injection site discolouration	1	0
Injection site discomfort	2	0
Injection site dryness	1	0
Injection site erythema	8	0
Injection site haemorrhage	1	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	1	0
Injection site indentation	1	0
Injection site induration	2	0
Injection site mass	13	0
Injection site nerve damage	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site nodule	1	0
Injection site pain	34	0
Injection site pallor	1	0
Injection site papule	1	0
Injection site paraesthesia	1	0
Injection site pruritus	3	0
Injection site rash	7	0
Injection site reaction	3	0
Injection site swelling	19	0
Mass conditions NEC		
Cyst	1	0
Mass	1	0
Nodule	3	0
Mucosal findings abnormal		
Mucosal inflammation	1	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	6	0
Oedema	7	0
Oedema peripheral	1	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	6	0
Discomfort	6	0
Facial discomfort	5	0
Facial pain	5	0
Pain	13	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	4	0
Adverse event	3	0
Drug ineffective	12	0
Drug ineffective for unapproved indication	1	0
Drug resistance	1	0
Drug tolerance	1	0
Therapeutic product effect delayed	1	0
Therapeutic response decreased	4	0
Therapeutic response increased	1	0
Therapeutic response shortened	4	0
Trophic disorders		
Atrophy	1	0
Dysplasia	1	0
General disorders SOC TOTAL	374	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
Hepatic disorders SOC TOTAL	1	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	19	0
Type I hypersensitivity	1	0
Type IV hypersensitivity reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
Immune system disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Infections		
<i>Atypical mycobacterial infections</i>		
Atypical mycobacterial infection	1	0
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Cellulitis	3	0
Cellulitis orbital	2	0
Folliculitis	1	0
<i>Clostridia infections</i>		
Botulism	5	0
<i>Coronavirus infections</i>		
COVID-19	4	0
COVID-19 pneumonia	1	0
<i>Dental and oral soft tissue infections</i>		
Oral infection	1	0
<i>Ear infections</i>		
Ear infection	1	0
Mastoiditis	1	0
Otitis media	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Fungal infections NEC</i>		
Onychomycosis	1	0
<i>Herpes viral infections</i>		
Oral herpes	2	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess rupture	1	0
Administration site infection	1	0
Infection	1	0
Injection site abscess	1	0
Injection site infection	1	0
Purulent discharge	1	0
Respiratory tract infection	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	1	0
Pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Injection site pustule	1	0
Rash pustular	1	0
<i>Upper respiratory tract infections</i>		
Pharyngitis	1	0
Sinusitis	2	0
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Viral infection	3	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Infections SOC TOTAL	55	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat stroke	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
Prescription drug used without a prescription	1	0
Product use in unapproved indication	1	0
Wrong technique in product usage process	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Neurological and psychiatric procedural complications</i>		
Mephisto sign	1	0
<i>Off label uses</i>		
Off label use	71	0
<i>Overdoses NEC</i>		
Overdose	14	0
Prescribed overdose	6	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	3	0
Incorrect dose administered	1	0
Incorrect route of product administration	7	0
Product administered at inappropriate site	2	0
Product administered by wrong person	1	0
Product administration error	2	0
<i>Product preparation errors and issues</i>		
Product preparation error	12	0
Product preparation issue	4	0
<i>Radiation injuries</i>		
Sunburn	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
Scar	2	0
Injuries SOC TOTAL	145	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	1	0
Heart rate irregular	1	0
Pulse abnormal	2	0
<i>Mineral and electrolyte analyses</i>		
Blood sodium decreased	1	0
<i>Physical examination procedures and organ system status</i>		
General physical condition abnormal	1	0
Weight decreased	3	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	1	0
Blood pressure increased	3	0
Investigations SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	5	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	1	0
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Feeding disorder	1	0
Malnutrition	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Lipoedema	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
<i>Bone disorders NEC</i>		
Bone loss	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	5	0
Joint stiffness	1	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	1	0
Muscle spasms	11	0
Muscle swelling	1	0
Muscle tightness	2	0
Muscle twitching	6	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	12	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mastication disorder	1	0
Muscle contracture	1	0
Musculoskeletal stiffness	8	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	4	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	4	0
Musculoskeletal pain	1	0
Neck pain	7	0
Pain in extremity	2	0
<i>Tendon disorders</i>		
Tendon discomfort	1	0
Muscle & tissue disorders SOC TOTAL	83	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Aural neoplasms benign</i>		
Cholesteatoma	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
Neoplasms SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Reflexes abnormal	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Cerebrovascular accident	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	4	0
Coordination abnormal	1	0
<i>Cortical dysfunction NEC</i>		
Apraxia	1	0
Dyslexia	1	0
Dyspraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Loss of consciousness	5	0
Syncope	10	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	2	0
Hypokinesia	1	0
Motor dysfunction	1	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	5	0
Facial paralysis	16	0
Facial paresis	11	0
Facial spasm	2	0
<i>Headaches NEC</i>		
Headache	72	0
Post-traumatic headache	1	0
Tension headache	2	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
<i>Migraine headaches</i>		
Migraine	9	0
Vestibular migraine	1	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	3	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	5	0
Dizziness	34	0
Head discomfort	5	0
Presyncope	4	0

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Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	3	0
Neuromuscular toxicity	8	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Formication	2	0
Hypoaesthesia	18	0
Paraesthesia	23	0
Reversed hot-cold sensation	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	3	0
<i>Parkinson's disease and parkinsonism</i>		
Reduced facial expression	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
Seizure	6	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	3	0
Neuralgia	3	0
Sensory disturbance	2	0
Sensory loss	1	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	4	0
Speech disorder	3	0
<i>Tremor (excl congenital)</i>		
Tremor	6	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	307	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 04-Sep-1998

MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	5	0

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Reaction Name	Total	Fatal
<i>Counterfeit, falsified and substandard products</i>		
Suspected counterfeit product	1	0
<i>Device issues NEC</i>		
Device dislocation	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	1	0
<i>Product packaging issues</i>		
Product packaging issue	1	0
<i>Product quality issues NEC</i>		
Product quality issue	3	0
Product substitution issue	1	0
null SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Breath holding	1	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	1	0
<i>Affect alterations NEC</i>		
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Anxiety	23	0
Nervousness	3	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	2	0
<i>Depressive disorders</i>		
Depression	3	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	13	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
Feeling of despair	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Trichotillomania	1	0
<i>Panic attacks and disorders</i>		
Panic attack	11	0
Panic reaction	2	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Psychiatric symptoms NEC</i>		
Psychiatric symptom	1	0
<i>Psychotic disorder NEC</i>		
Substance-induced psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Stress disorders</i>		
Post-traumatic stress disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	3	0
<i>Thinking disturbances</i>		
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	82	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Urinary abnormalities</i>		
Chromaturia	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	28	0
Hyperventilation	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
Productive cough	1	0
<i>Diaphragmatic disorders</i>		
Diaphragmatic disorder	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Nasal oedema	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus disorder	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Respiratory tract disorders NEC</i>		
Pulmonary mass	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Oropharyngeal pain	3	0
Paranasal sinus discomfort	2	0
Sneezing	1	0
Throat tightness	4	0
Respiratory disorders SOC TOTAL	58	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	2	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	5	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	2	0
<i>Connective tissue disorders</i>		
Brow ptosis	8	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Pain of skin	1	0
Skin burning sensation	3	0
Skin discolouration	5	0
Skin disorder	1	0
Skin indentation	2	0
Skin induration	1	0
Skin lesion	4	0
Skin necrosis	1	0
Skin swelling	4	0
Skin tightness	5	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
Dermatitis contact	1	0
Skin irritation	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
<i>Erythemas</i>		
Erythema	17	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Lipodystrophies</i>		
Facial wasting	1	0
<i>Panniculitides</i>		
Panniculitis	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	4	0
<i>Pruritus NEC</i>		
Pruritus	10	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	12	0
Rash erythematous	1	0
Rash macular	8	0
Rash papular	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash pruritic	2	0
Rash vesicular	1	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Adiposis dolorosa	1	0
Skin mass	3	0
<i>Skin dystrophies</i>		
Skin wrinkling	5	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	2	0
<i>Urticarias</i>		
Urticaria	7	0
Skin disorders SOC TOTAL	143	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Impaired driving ability	1	0
Impaired work ability	1	0
Loss of personal independence in daily activities	1	0
<i>Social issues NEC</i>		
Patient dissatisfaction with treatment	1	0
Social circumstances SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Dental and gingival therapeutic procedures</i>		
Endodontic procedure	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Skin cosmetic procedure	1	0
<i>Therapeutic procedures NEC</i>		
Cyst drainage	1	0
Mass excision	1	0
Surgical & medical procedures SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific vascular disorders NEC</i>		
Angiopathy	1	0
Capillary fragility	1	0
Superficial vein prominence	1	0
Vasodilatation	1	0
Vein collapse	1	0
Vein discolouration	1	0
Vein disorder	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	2	0
Hot flush	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	4	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	22	0
TOTAL REACTIONS FOR DRUG	1754	0
TOTAL REPORTS	396	