

# Case Series Drug Analysis Print

**Name: Botox**

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Botox: UK spontaneous ADRs for Botox with a cosmetic indication

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
Lymphatic disorder	1	0
Lymphatic obstruction	1	0
<b>Blood disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	8	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
 Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	3	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	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	5	0
Vertigo	6	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
<b>Ear disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
Eyelid ptosis	14	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	1	0
Uveitis	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	4	0
Lacrimation increased	2	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	1	0
Erythema of eyelid	1	0
Eyelid oedema	1	0
Swelling of eyelid	4	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye oedema	1	0
Eye pain	3	0
Eye swelling	9	0
Eyelid disorder	2	0
Eyelids pruritus	1	0
Ocular discomfort	2	0
Periorbital oedema	1	0
Periorbital swelling	8	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye irritation	1	0
Eye pruritus	2	0
Ocular hyperaemia	2	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Photophobia	3	0
<i><b>Orbital structural change, deposit and degeneration</b></i>		
Lid sulcus deepened	1	0
Orbital swelling	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Vision blurred	15	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	2	0
Visual impairment	6	0
<b>Eye disorders SOC TOTAL</b>	<b>96</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<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	3	0
<i>Dyspeptic signs and symptoms</i>		
Eructation	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Anal incontinence	1	0
Dysphagia	10	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	14	0
Vomiting	4	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	5	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	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
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>55</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<b>Administration site reactions NEC</b>		
Administration site necrosis	1	0
<b>Application and instillation site reactions</b>		
Application site swelling	1	0
<b>Asthenic conditions</b>		
Asthenia	7	0
Chronic fatigue syndrome	1	0
Fatigue	12	0
Malaise	15	0
<b>Febrile disorders</b>		
Pyrexia	3	0
<b>Feelings and sensations NEC</b>		
Chills	1	0
Feeling abnormal	5	0
Feeling hot	1	0
Thirst	2	0
<b>Gait disturbances</b>		
Gait disturbance	1	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	3	0
Crepitations	1	0
Deformity	1	0
Illness	5	0
Influenza like illness	12	0
Peripheral swelling	1	0
Swelling	4	0
Swelling face	6	0
Unevaluable event	1	0
<b>Healing abnormal NEC</b>		
Impaired healing	1	0
<b>Inflammations</b>		
Inflammation	3	0
Papillitis	1	0
<b>Injection site reactions</b>		
Injection site bruising	4	0
Injection site discomfort	1	0
Injection site erythema	3	0
Injection site granuloma	1	0
Injection site injury	1	0
Injection site mass	3	0
Injection site nodule	1	0
Injection site pain	5	0
Injection site paraesthesia	1	0
Injection site pruritus	1	0
Injection site rash	3	0
Injection site reaction	1	0
Injection site swelling	9	0
Injection site ulcer	1	0
<b>Mass conditions NEC</b>		
Mass	1	0
<b>Oedema NEC</b>		
Face oedema	2	0
Oedema	2	0



# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
 Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	2	0
Chest pain	2	0
Discomfort	4	0
Facial discomfort	1	0
Facial pain	5	0
Pain	9	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	3	0
Adverse event	1	0
Drug effect less than expected	1	0
Drug ineffective	6	0
Drug ineffective for unapproved indication	1	0
Therapeutic response decreased	1	0
Therapeutic response increased	1	0
Therapeutic response shortened	2	0
<i><b>Trophic disorders</b></i>		
Dysplasia	1	0
<b>General disorders SOC TOTAL</b>	<b>169</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	6	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Atypical mycobacterial infections</b></i>		
Mycobacterium abscessus infection	1	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	1	0
Cellulitis orbital	1	0
Folliculitis	1	0
<i><b>Clostridia infections</b></i>		
Botulism	3	0
<i><b>Coronavirus infections</b></i>		
COVID-19	3	0
COVID-19 pneumonia	1	0
<i><b>Dental and oral soft tissue infections</b></i>		
Oral infection	1	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
Mastoiditis	1	0
Otitis media	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	1	0
<i><b>Fungal infections NEC</b></i>		
Onychomycosis	1	0
<i><b>Herpes viral infections</b></i>		
Oral herpes	2	0
<i><b>Infections NEC</b></i>		
Abscess	1	0
Administration site infection	1	0
Infection	1	0
Injection site abscess	1	0
Respiratory tract infection	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Pneumonia	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Subcutaneous abscess	1	0
<i><b>Upper respiratory tract infections</b></i>		
Tonsillitis	1	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	2	0
<i><b>Viral infections NEC</b></i>		
Gastroenteritis viral	1	0
Viral infection	1	0
<b>Infections SOC TOTAL</b>	<b>33</b>	<b>0</b>

# Case Series Drug Analysis Print

**Name: Botox**

Report Run Date: 11-Apr-2024  
 Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Eye injuries NEC</b></i>		
Eye contusion	1	0
<i><b>Heat injuries (excl thermal burns)</b></i>		
Heat stroke	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	1	0
Wrong technique in product usage process	2	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	1	0
<i><b>Neurological and psychiatric procedural complications</b></i>		
Mephisto sign	1	0
<i><b>Off label uses</b></i>		
Off label use	23	0
<i><b>Overdoses NEC</b></i>		
Prescribed overdose	1	0
<i><b>Poisoning and toxicity</b></i>		
Toxicity to various agents	1	0
<i><b>Product administration errors and issues</b></i>		
Incorrect route of product administration	1	0
Product administered at inappropriate site	2	0
Product administration error	1	0
<i><b>Product preparation errors and issues</b></i>		
Product preparation error	7	0
<i><b>Skin injuries NEC</b></i>		
Scar	1	0
<b>Injuries SOC TOTAL</b>	<b>44</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate irregular	1	0
<i>Physical examination procedures and organ system status</i>		
General physical condition abnormal	1	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	2	0
<b>Investigations SOC TOTAL</b>	<b>6</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	5	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Histamine intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Bone related signs and symptoms</i>		
Pain in jaw	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle spasms	5	0
Muscle swelling	1	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	6	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Muscle contracture	1	0
Musculoskeletal stiffness	4	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	2	0
Musculoskeletal pain	1	0
Neck pain	6	0
Pain in extremity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>



# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Aural neoplasms benign</i>		
Cholesteatoma	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>4</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	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	2	0
Syncope	3	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	9	0
Facial paresis	8	0
Facial spasm	1	0
<i>Headaches NEC</i>		
Headache	45	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	2	0
<i>Migraine headaches</i>		
Migraine	7	0
Vestibular migraine	1	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	19	0
Head discomfort	2	0
Presyncope	2	0
<i>Neuromuscular disorders NEC</i>		
Neuromuscular toxicity	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Hypoaesthesia	5	0
Paraesthesia	12	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Seizure	3	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	3	0
Neuralgia	1	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	3	0

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Speech disorder	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	5	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>158</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>2</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Counterfeit, falsified and substandard products</i></b>		
Suspected counterfeit product	1	0
<b><i>Product quality issues NEC</i></b>		
Product quality issue	1	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Affect alterations NEC</b></i>		
Inappropriate affect	1	0
<i><b>Anxiety symptoms</b></i>		
Anxiety	16	0
Nervousness	3	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	1	0
Disorientation	1	0
<i><b>Depressive disorders</b></i>		
Depression	3	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	7	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	1	0
Emotional distress	1	0
<i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i>		
Social fear	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	1	0
<i><b>Obsessive-compulsive disorders and symptoms</b></i>		
Trichotillomania	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic attack	4	0
Panic reaction	2	0
<i><b>Perception disturbances NEC</b></i>		
Autoscopy	1	0
<i><b>Psychiatric symptoms NEC</b></i>		
Psychiatric symptom	1	0
<i><b>Stress disorders</b></i>		
Post-traumatic stress disorder	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	3	0
<i><b>Thinking disturbances</b></i>		
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>50</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024

Data Lock Date: 09-Apr-2024 18:30:03

Earliest Reaction Date: 18-Nov-2000

MedDRA Version: MedDRA 26.1

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

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
 Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	14	0
Hyperventilation	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Paranasal sinus discomfort	1	0
Throat tightness	3	0
<b>Respiratory disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>



# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
Dermatitis acneiform	1	0
<b><i>Alopecias</i></b>		
Alopecia	1	0
<b><i>Angioedemas</i></b>		
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	1	0
Hyperhidrosis	3	0
<b><i>Bullous conditions</i></b>		
Blister	2	0
<b><i>Connective tissue disorders</i></b>		
Brow ptosis	2	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Pain of skin	1	0
Skin burning sensation	2	0
Skin discolouration	1	0
Skin indentation	1	0
Skin lesion	1	0
Skin tightness	2	0
Skin warm	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis contact	1	0
<b><i>Erythemas</i></b>		
Erythema	7	0
<b><i>Lipodystrophies</i></b>		
Facial wasting	1	0
<b><i>Photosensitivity and photodermatitis conditions</i></b>		
Photosensitivity reaction	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	4	0
Rash pruritic	1	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	2	0
<b><i>Skin dystrophies</i></b>		
Skin wrinkling	3	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Loss of personal independence in daily activities	1	0
<i>Social issues NEC</i>		
Patient dissatisfaction with treatment	1	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Eye therapeutic procedures NEC</i>		
Eye operation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Skin cosmetic procedure	1	0
<i>Therapeutic procedures NEC</i>		
Mass excision	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>3</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Botox

Report Run Date: 11-Apr-2024  
 Earliest Reaction Date: 18-Nov-2000

Data Lock Date: 09-Apr-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Vasodilatation	1	0
Vein discolouration	1	0
Vein disorder	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>806</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>191</b>	