

Human Body

BOTOX[®]/BOTOX[®] Cosmetic (Botulinum Toxin Type A)

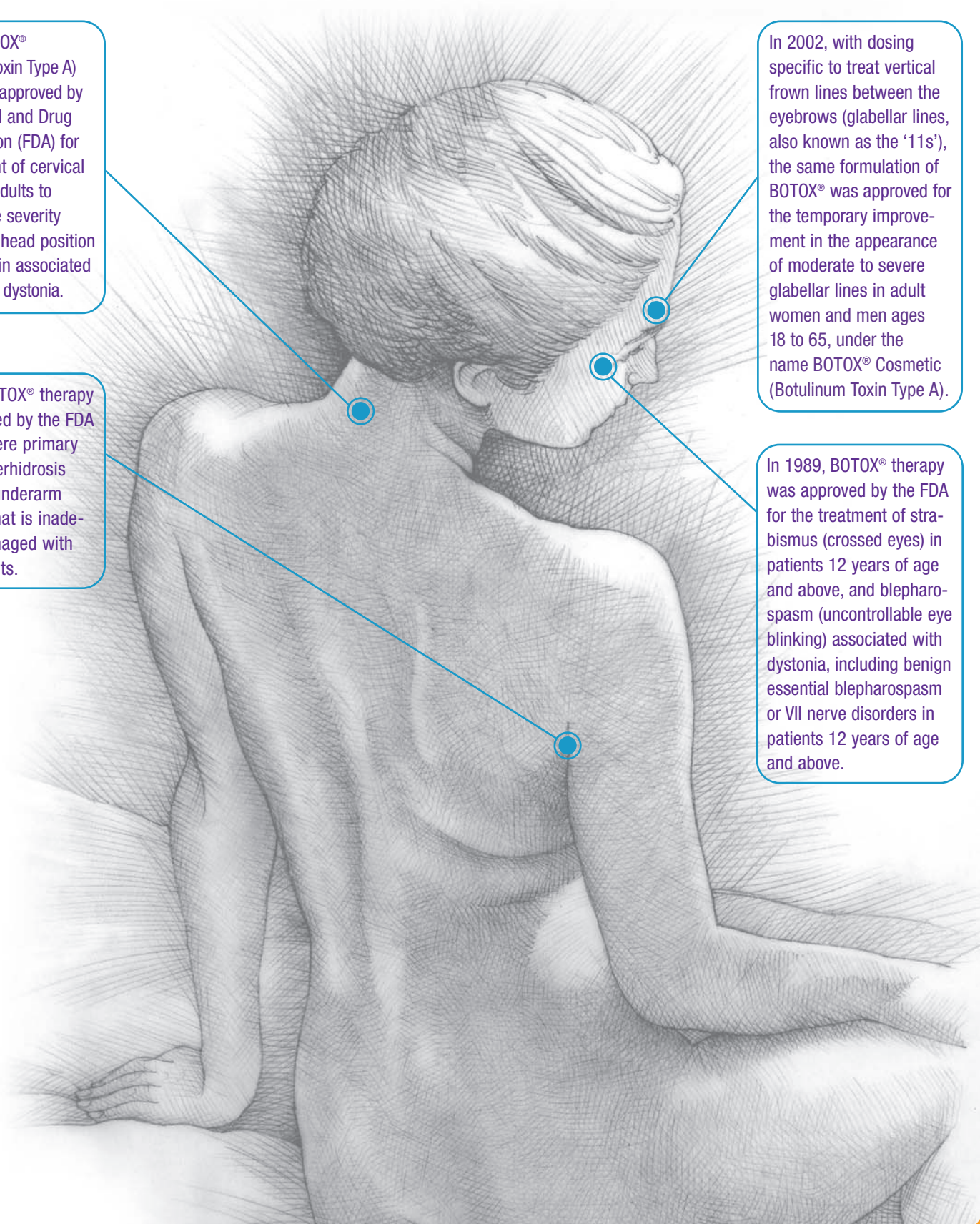
Approved Uses in the U.S.

In 2000, BOTOX[®] (Botulinum Toxin Type A) therapy was approved by the U.S. Food and Drug Administration (FDA) for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

In 2004, BOTOX[®] therapy was approved by the FDA to treat severe primary axillary hyperhidrosis (excessive underarm sweating) that is inadequately managed with topical agents.

In 2002, with dosing specific to treat vertical frown lines between the eyebrows (glabellar lines, also known as the '11s'), the same formulation of BOTOX[®] was approved for the temporary improvement in the appearance of moderate to severe glabellar lines in adult women and men ages 18 to 65, under the name BOTOX[®] Cosmetic (Botulinum Toxin Type A).

In 1989, BOTOX[®] therapy was approved by the FDA for the treatment of strabismus (crossed eyes) in patients 12 years of age and above, and blepharospasm (uncontrollable eye blinking) associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.



About BOTOX®

BOTOX® is a medical product that contains tiny amounts of highly purified botulinum toxin protein refined from a bacterium. The product is administered in small therapeutic doses by injection directly into the affected area, and works by blocking the release of acetylcholine (a neurotransmitter that signals the muscles to contract) at the neuromuscular junction.

BOTOX® therapy was granted approval by the FDA in 1989 for the treatment of strabismus (crossed eyes) and blepharospasm (uncontrollable eye blinking) associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above. BOTOX® has since received approval in December 2000 for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia. In 2002, with dosing specific to treat frown lines between the eyebrows, the product was approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines (the vertical “frown lines” between the eyebrows) in adult women and men ages 18 to 65, under the name of BOTOX® Cosmetic. More recently, in July 2004, BOTOX® was granted FDA approval for the treatment of severe primary axillary hyperhidrosis (excessive underarm sweating) that is inadequately managed with topical agents.

Important Risk Information

BOTOX® and BOTOX® Cosmetic treatment is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any ingredient in the formulation. Serious and/or immediate hypersensitivity reactions have been rarely reported. These reactions include anaphylaxis, urticaria, soft tissue edema, and dyspnea. If such a reaction occurs further injection of BOTOX® or BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. BOTOX® and BOTOX® Cosmetic should only be diluted with 0.9 percent non-preserved sodium chloride. Individuals with peripheral motor neuropathic diseases (e.g., amyotrophic lateral sclerosis, or motor neuropathy) or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should only receive BOTOX® or BOTOX® Cosmetic with caution. Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of BOTOX® or BOTOX® Cosmetic. There have been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

BOTOX® for Blepharospasm in Patients ≥ 12 Years of Age: Reduced blinking from BOTOX® injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal perforation. The most frequently reported treatment-related adverse reactions in these patients are ptosis (20.8%), superficial punctate keratitis (6.3%) and eye dryness (6.3%).

BOTOX® for Strabismus in Patients ≥ 12 Years of Age: Inducing paralysis in one or more extraocular muscles may produce spatial disorientation, double vision or past pointing. The most commonly reported adverse effects are ptosis (16%) and vertical deviation (17%).

BOTOX® for Cervical Dystonia in Adults: There have been rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube. The most frequently reported adverse reactions in patients with cervical dystonia are dysphagia (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

BOTOX® for Severe Primary Axillary Hyperhidrosis Inadequately Managed with Topical Agents: The most frequently reported adverse events (3-10%) are injection site pain and hemorrhage, non-axillary sweating, infection, pharyngitis, flu syndrome, headache, fever, neck or back pain, pruritus, and anxiety.

BOTOX® Cosmetic for Temporary Improvement in the Appearance of Moderate to Severe Frown Lines Between the Brows in adults ages 18 to 65. The most frequently reported adverse events are blepharoptosis (3.2%) and nausea (3%).

Please see enclosed full prescribing information for BOTOX® and BOTOX® Cosmetic.