

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.

The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.

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 neuro-muscular junction.

BOTOX® neurotoxin therapy was granted approval by the FDA in 1989 for the treatment of strabismus (crossed eyes) and blepharospasm (uncontrollable eye blinking) associated with dystonia.

BOTOX® neurotoxin 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 men and women ages 18 to 65, under the name 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 Safety Information

Who should not be treated with BOTOX®

BOTOX® injections should not be given to people who have an infection where the physician proposes to inject. They should not be given to people who are known to be sensitive to any ingredient in the BOTOX® product.

Warnings

Serious heart problems and serious allergic reactions have been reported rarely. If you think you are having an allergic reaction or other reactions, such as difficulty swallowing, speaking, or breathing, call your doctor immediately. Patients with certain neuromuscular disorders such as ALS, myasthenia gravis, or Lambert-Eaton syndrome may be at increased risk of serious side effects.

Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia (difficulty swallowing) and respiratory compromise from typical doses of BOTOX®.

Dysphagia (difficulty swallowing) is a commonly reported adverse event following treatment of cervical dystonia patients with all botulinum toxins. In these patients, there are reports of rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube.

Precautions

Patients or caregivers should be advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

Side Effects

Localized pain, infection, inflammation, tenderness, swelling, redness and/or bruising may be associated with the injection.

In cervical dystonia, the most common side effects following injection include difficulty swallowing (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

In blepharospasm, the most common side effects following injection include ptosis (20.8%), inflammation of the cornea (6.3%), and eye dryness (6.3%).

In strabismus, the most common side effects following injection include ptosis (15.7%) and vertical deviation (16.9%).

In severe primary axillary hyperhidrosis, the most common side effects (3-10% of patients) following injection include injection-site pain and bleeding, non-underarm sweating, infection, sore throat, flu, headache, fever, neck or back pain, itching and anxiety.

The most common side effects following BOTOX® Cosmetic injections include temporary eyelid droop and nausea.

Please see accompanying full product information for BOTOX® and BOTOX® Cosmetic, also available at www.BOTOX.com and www.BOTOXCosmetic.com.