



BOTOX[®] (Botulinum Toxin Type A) FACT SHEET

About BOTOX[®]

- BOTOX[®] (Botulinum Toxin Type A) is a simple, minimally invasive treatment that may deliver effective results to a wide range of patients suffering from certain neurological disorders.
- BOTOX[®] is a purified protein derived from the bacterium *Clostridium botulinum*. Type A is one of the seven distinct antigenic botulinum toxins produced by different strains of the bacterium.
- BOTOX[®] decreases muscle activity by blocking overactive nerve impulses that trigger excessive muscle contractions or glandular activities and is administered in a few injections directly into the affected area.

BOTOX[®] for Therapeutic Use

- Allergan's BOTOX[®] neurotoxin is an important versatile medicine with 20 years of successful clinical experience in certain therapeutic applications.
- In the United States, BOTOX[®] neurotoxin therapy was granted approval in 1989 by the U.S. Food and Drug Administration (FDA) for the treatment of strabismus (crossed eyes) and blepharospasm (uncontrollable eye blinking). BOTOX[®] neurotoxin has since received U.S. FDA 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. Most recently, in July 2004, BOTOX[®] neurotoxin was granted U.S. FDA approval for the treatment of severe primary axillary hyperhidrosis (excessive underarm sweating) that is inadequately managed with topical agents.

Please refer to important BOTOX[®] information on page 3



- Around the world, BOTOX[®] has been approved in approximately 80 countries for 21 different indications.
- Today, Allergan is working in collaboration with many academic institutions, researchers, scientists and physicians to continue exploring the full therapeutic potential of this versatile medicine and to develop new medical uses for BOTOX[®] in other areas where there is a need for new treatment options.

BOTOX[®] Cosmetic (Botulinum Toxin Type A) for Aesthetic Use

- With dosing specific to treat the stubborn frown lines between the brows, the same product is now marketed as BOTOX[®] Cosmetic in the United States and Canada, as VISTABEL[®] in France, Spain, Switzerland and many other European countries, and as VISTABEX[®] in Italy.
- In 2002, BOTOX[®] Cosmetic was approved by the U.S. 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. The glabellar lines, which often look like the number “11,” can have a negative effect on one’s overall facial appearance by creating a sad, angry, or tired impression.
- When administered for this use, BOTOX[®] Cosmetic creates a temporary smoothed and improved appearance of the wrinkle-causing muscles between the brows.

How BOTOX[®] Works

- BOTOX[®] neurotoxin blocks overactive nerve impulses that cause excessive muscle contractions or glandular activity by selectively preventing the release of the neurotransmitter acetylcholine at the neuromuscular junction and temporarily inhibiting the targeted muscle or gland activity.
- BOTOX[®] is administered in small therapeutic doses by intramuscular or intradermal injection directly into the affected area, depending on the indication, producing a typically reversible decrease of muscle or gland activity.



- The therapeutic effect of BOTOX[®] is temporary and lasts up to approximately three to 6.7 months, depending on the individual patient and indication. Over time the nerve inhibition produced by BOTOX[®] neurotoxin is reversed as nerve endings recover and begin to release acetylcholine again, at which time another injection of BOTOX[®] may be needed to maintain therapeutic effect.

Important BOTOX[®] and BOTOX[®] Cosmetic (Botulinum Toxin Type A) Information

BOTOX[®] is approved for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

BOTOX[®] is approved for the treatment of strabismus and blepharospasm 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.

And BOTOX[®] is approved for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

BOTOX[®] Cosmetic is approved for the temporary treatment of moderate to severe frown lines between the brows in people ages 18 – 65.

Important Safety Information

Who should not be treated with BOTOX[®]

BOTOX[®] and BOTOX[®] Cosmetic 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[®].

Continued on next page

Warnings (continued)

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.

BOTOX[®] therapy should only be administered by a trained and qualified physician. Please see accompanying full product information for BOTOX[®] and BOTOX[®] Cosmetic, also available by visiting www.BOTOX.com and www.BOTOXCosmetic.com or by visiting www.BOTOXGlobalNews.com, selecting the country of interest and clicking on "Country Resources/Prescribing Information."

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