



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® is an important versatile medicine with more than 18 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) associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above. BOTOX® 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. More 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.

- In the United States, BOTOX[®] is currently being investigated for the treatment of additional medical conditions, including headache/migraine, post-stroke spasticity, and overactive bladder.
- Around the world, BOTOX[®] has been approved in more than 75 countries for 20 different indications treating many patients who suffer from certain neurological disorders.

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

- With dosing specific to treat 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 from approximately one to six 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.

BOTOX[®] therapy should only be administered by a trained and qualified physician. Further product and prescribing information is available by visiting www.Botox.com or 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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For further information please contact Allergan, Inc.:

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| Caroline Van Hove: | 714-264-5134 |
| Cathy Taylor (BOTOX[®]): | 714-246-5551 |
| Leslie Bryant (BOTOX[®] Cosmetic): | 714-246-6948 |