



BOTOX[®] Cosmetic (Botulinum Toxin Type A) Fact Sheet

- More than 13 million aesthetic procedures with BOTOX[®] Cosmetic (botulinum toxin type A) have been administered since the product was first approved in 2002 in the United States for temporary treatment of moderate to severe glabellar lines (the vertical “frown lines” between the eyebrows) in adults 18 to 65.ⁱ
- According to the American Society for Aesthetic Plastic Surgery (ASAPS), more than three million BOTOX[®] Cosmetic treatments were administered in 2006 alone.ⁱⁱ
- Ninety-seven percent of patients were definitely satisfied with BOTOX[®] Cosmetic treatments, according to a survey of approximately 1,000 patients conducted by the research arm of ASAPS.ⁱⁱⁱ
- BOTOX[®] Cosmetic, approved for the temporary treatment of glabellar lines, is the same medicine that is used to treat patients with neurological conditions under the name BOTOX[®]. It is, however, administered in much smaller doses for aesthetic use. The approved doses of BOTOX[®] for medical uses are significantly greater than the approved dose for an aesthetic procedure.
- BOTOX[®] Cosmetic is a simple, minimally invasive injectable treatment that creates a temporary smoothed and improved appearance of the wrinkle-causing muscles between the brows that lasts up to four months. Most side effects are temporary and typically associated with the injection itself, such as localized pain, tenderness, redness and/or bruising. (See full safety information provided below).
- Since its first approval more than 18 years ago, reports of serious adverse events in patients receiving BOTOX[®] have been rare.
- BOTOX[®] Cosmetic should only be administered[®] by a licensed health care professional (HCP) who is well trained in the anatomy of the face.

About the FDA Safety Review of Botulinum Toxin Products in the United States:

- As you may know, the U.S. Food and Drug Administration (FDA) recently issued a news release regarding its ongoing safety review of botulinum toxin treatments in the United States, including BOTOX[®] and BOTOX[®] Cosmetic (botulinum toxin type A).
- As part of the FDA's ongoing commitment to safety evaluation and communication to the public, the FDA recently adopted a routine protocol to provide an "early communication" regarding safety or other related reviews, often before any conclusions are or can be made. The FDA will communicate its conclusions and resulting recommendations after its review of the data has been completed.
- The FDA inquiry relates primarily to small number of high dose medical uses of BOTOX[®] that have occurred over the past 18 years, particularly for the management of juvenile cerebral palsy (JCP) and other large muscle, lower limb spasticities. Use of botulinum toxins for treatment of limb spasticity (severe arm and leg muscle spasms) in children or adults is not an approved use in the United States. The FDA indicated that this JCP population often consists of sick and compromised patients. The FDA also indicated that these reactions may relate to very high doses. By way of comparison, some of these adverse event reports, submitted promptly by Allergan to the FDA, indicated doses of greater than 20-100 times that of a typical aesthetic use on a per kilogram of body weight basis. However, the FDA will review certain adverse event reports for both unapproved and approved uses of BOTOX[®] and BOTOX[®] Cosmetic.
- Furthermore, it is important to understand that a report of an adverse event following treatment with BOTOX[®] and BOTOX[®] Cosmetic does not by itself mean that the drug caused the event, but that the event occurred after treatment with the drug so it needs to be investigated. The FDA is not advising HCPs to stop using BOTOX[®] Cosmetic.
- In its entire history, there has never been a single reported death where a causal link to BOTOX[®] Cosmetic was established.
- As the product labeling for BOTOX[®] Cosmetic already states, patients with pre-existing neuromuscular disorders may be at increased risk of clinically significant systemic effects from typical doses of BOTOX[®] Cosmetic. Patients should always consult with their physician to see if treatment with BOTOX[®] Cosmetic is right for them.

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

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

BOTOX[®] Cosmetic is the only product of its type approved by the U.S. Food and Drug Administration for the treatment of moderate to severe frown lines between the brows. BOTOX[®] Cosmetic should only be administered by a trained and qualified health care provider.

Important BOTOX[®] Cosmetic Safety Information

Serious heart problems and serious allergic reactions have been reported rarely. If you think you're having an allergic reaction or other unusual symptoms, such as difficulty swallowing, speaking or breathing, call your doctor immediately. The most common side effects following injection include temporary eyelid droop and nausea. Localized pain, infection, inflammation, tenderness, swelling, redness and/or bleeding/bruising may be associated with the injection. Patients with certain neuromuscular disorders such as ALS, myasthenia gravis or Lambert-Eaton syndrome may be at increased risk of serious side effects.

For full prescribing information on BOTOX[®] Cosmetic, please visit www.BOTOXCosmetic.com

© 2008 Allergan, Inc. Irvine, CA 92612. ® marks owned by Allergan, Inc.

ⁱ American Society for Aesthetic Plastic Surgery <http://www.surgery.org>

ⁱⁱ American Society for Aesthetic Plastic Surgery Quick Facts <http://www.surgery.org/download/2006stats.pdf>

ⁱⁱⁱ Aesthetic Surgery Education & Research Foundation press release "First-of-its-kind Survey Finds That BOTOX Cosmetic has Gone Mainstream" Released 04/28/06