

BOTOX Cosmetic - Now FDA Approved for Aesthetic Treatment

Over the past year, the number of BOTOX® treatments has increased by 60 percent. Patients are flocking, particularly during the fall and winter months, to reduce the appearance of wrinkles. This past April, the U.S. Food and Drug Administration (FDA) approved BOTOX® for "the temporary improvement in the appearance of moderate to severe glabellar lines [the vertical lines between eyebrows] in adult men and women years of age or younger." For this use, the product will be marketed as BOTOX® Cosmetic.

BOTOX®, derived from botulinum toxin A, is manufactured by Allergan, Inc. and has been used successfully over the past 10 years for various conditions.

"Our successful clinical work shows that BOTOX® Cosmetic is safe and effective for this aesthetic use," comments Lester J. Kaplan, PhD, Allergan's President of Research and Development and Global BOTOX®. "Along with the previous approvals in the U.S. for BOTOX® in the treatment of certain neurological disorders, this new indication firmly establishes the versatility of the product."

Who will benefit from BOTOX® Cosmetic? Patients who have wrinkles between their eyebrows tend to appear tired or upset; they have a permanent scowl. BOTOX® Cosmetic can provide a solution. "I decided to have BOTOX® Cosmetic treatments because I was tired of everyone asking me, 'What's wrong? Are you upset?' I am thrilled that there is a simple treatment that I can have done on my lunch hour with no recovery time," says Linda H. "And when people see me now they comment on how confident and calm I look."

Wrinkles between the eyebrows are caused by contracting muscles in the forehead, the corrugator and procerus muscles. Small injections of the purified protein are put into those muscles. BOTOX® Cosmetic blocks the nerve impulses that trigger the muscle



Blepharospasm: This movement disorder affects the eyelids with involuntary spasms of the muscles controlling the eyelid. As the condition progresses, the spasms may intensify, forcing the eyelids to remain closed for long periods of time, causing substantial visual obstruction. BOTOX® may be injected into the affected eye muscles in order to reduce the spasms and excessive blinking. The success rate is between 90 to 95 percent, with effects lasting approximately three months. As with most BOTOX® treatments, injections may be repeated as long as the patient is responding well.

Strabismus Strabismus is characterized by a deviation in alignment of the eyes; the eyes turn in different directions. In adults, strabismus is caused by diabetes, head trauma, stroke, brain tumor, or other diseases affecting nerves that control eye muscles. Two percent of children are diagnosed with strabismus; four percent of adults have strabismus, which is more commonly referred to as a wandering eye, lazy eye, or crossed-eye. BOTOX® therapy is thought to affect muscle pairs by relaxing the muscle causing it to lengthen and the corresponding muscle to shorten, aiding in the alignment of the eye. Treatment lasts approximately three months.

Hyperhidrosis: Hyperhidrosis is a chronic disorder of excessive sweating that may affect any body part, particularly the underarms, palms, soles of the feet, and face. Roughly one percent of the world's population suffer from hyperhidrosis. BOTOX® therapy is administered via tiny injections within the skin of the affected area to block the release of the chemical that signals the perspiration. BOTOX® can dramatically improve the quality of life for

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contractions. The result is a smooth, improved appearance between the eyebrows. The procedure is minimally invasive, quick, and may have results that last up to four months.

See your facial plastic surgeon for more information. Check out the inside story on pages 2 and 3 for more information on the many uses of botulinum toxin.

Botulinum Toxin A has Multiple Uses

The BOTOX® product is a sterile, purified protein derived from the bacterium, *Clostridium botulinum*. Over the past decade, it has proven to be an effective treatment for various conditions, including wrinkles, blepharospasm (excessive blinking), strabismus (misaligned eyes), hyperhidrosis (excessive sweating), cervical dystonia (disorder of head and neck muscles), and chronic and migraine headaches.

Allergan, Inc. manufactures BOTOX®/BOTOX® Cosmetic and explains that "normally your brain sends electrical messages to your muscles so that they can contract and move. The electrical message is transmitted to the muscle by a substance called acetylcholine. BOTOX® works to block the release of acetylcholine and, as a result, the muscle does not receive the message to contract. This means that the muscle spasms stop or are greatly reduced after using BOTOX®." This relaxation of the muscle, depending on the area for which it is used, typically lasts for several months.

Brow Furrow: Creases and wrinkles that are produced by facial expression muscles - repeatedly furrowing the skin - may be treated by reducing the contraction of distinct muscles. Now marketed for treatment in the brow area as BOTOX® Cosmetic, it is an effective treatment to relax the contracting muscles and temporarily reduce or eliminate previous skin creasing. BOTOX® Cosmetic may take several days to have its effect. In clinical studies, 82 percent of people noticed an improvement after a week. The results last between three to four months in most individuals. BOTOX® Cosmetic was approved by the FDA in April 2002 for the temporary improvement of glabellar lines (vertical lines between eyebrows).



those suffering from this disease with effects lasting between six and eight months with high patient satisfaction.

Cervical Dystonia: Cervical dystonia (CD) is a disorder characterized by spasms of the neck muscles. The muscle contractions force the head into abnormal positions and can be painful. BOTOX® therapy blocks the nerve impulses that trigger muscle hyperactivity. The treatment provides patients with improved head positioning, ability to function, and reduced pain. BOTOX® was approved by the FDA for treating CD in 2000. The effects last approximately three months.

Chronic Headaches and Migraines: The American Headache Society recently reported that BOTOX® injections given every three months appear to prevent up to 92 percent of debilitating headaches in patients that do not respond to other medications. Migraine headaches affect about 17 percent of women and six percent of men in the United States. Approximately five percent of the population have chronic daily headaches. BOTOX® works by relaxing the muscles for about three months. It is injected into muscles around the eyes, forehead, and sometimes the jaw. Patients whose headaches involve the entire head get additional injections in the upper back, neck, and shoulders. Allergan is currently in the process of developing a use of BOTOX® in treating headaches.

BOTOX® is a therapeutic, muscle-relaxing agent that is having positive results in treating various muscle disorders. Wrinkles formed by dynamic muscles (in motion), such as glabellar lines when we frown or crows feet when we smile or squint can be temporarily smoothed out with BOTOX® injections. The results, although temporary, will provide a smoother, younger appearance that will match your young spirit. Due to the nonsurgical nature of treatment, it is quick with no recovery time. If you have a condition that you feel might benefit from BOTOX®, please see your facial plastic surgeon.

History

- 1822. Justinus Kerner introduced the concept of using botulinum toxin for therapeutic purposes
- 1949. Discovered that botulinum toxin blocks neuromuscular



- transmission
- 1981. Botulinum toxin is studied to treat strabismus (crossed or lazy eye)
 - 1989. FDA approves BOTOX®: (botulinum toxin type A) for treating strabismus and blepharospasm (uncontrolled blinking)
 - 2000. FDA approves BOTOX®: for pain associated with cervical dystonia (abnormal contractions/spasms of the neck muscles)
 - 2002. FDA approves BOTOX®: Cosmetic for the treatment of glabellar lines (vertical lines between the eyebrows)