

INFORMED-CONSENT-BOTOX INJECTION (*Botulina* Toxin Type A)

Clostridia botulina bacteria produce a class of chemical compounds known as “toxins”. The *Botulina* Type A Toxin (BOTOX®, Allergan) is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle paralysis generally lasts for approximately three to four months. Continuing treatments are necessary in order to maintain the effect of BOTOX® over time.

As of April 2002, it has been FDA approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups. Other areas of the face and body such as crow’s feet wrinkles are cosmetically treated with BOTOX®. BOTOX® injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region and forehead. BOTOX® cannot stop the process of aging. It can, however, temporarily diminish the look of wrinkles caused by muscle groups.

THE APPOINTMENT

Typically a BOTOX® appointment takes 15-30 minutes depending on the number of areas that are treated. Several tiny “pokes” feeling similar to a “bee sting” are administered to the area(s). After the injections, one may return to work or daily activity however, one should avoid: lying down, pressing or massaging the injection site, strenuous activity (exercise) for 2 hours following treatment.

RISKS OF BOTOX INJECTIONS

Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual’s choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following complications, you must be aware of the risks, potential complications, and consequences of BOTOX® injections.

- It is possible, though unusual, to have a bleeding episode from a BOTOX® injection. Bruising in soft tissues may occur. Should you develop post-injection bleeding, do not take any aspirin or anti-inflammatory as this may contribute to a greater risk of a bleeding problem.
- BOTOX® may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. BOTOX® has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia)
- Some patients experience difficulties closing their eyelids after BOTOX® injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery might be necessary.
- Individuals who normally have dry eyes may be advised to use special caution in considering BOTOX® injections around the eyelid region.
- Muscles that raise the eyelid may be affected by BOTOX®, should this material migrate downward from other injection areas.
- Double vision may be produced if the BOTOX® material migrates into the region of muscles that control movements of the eyeball.
- Abnormal looseness of the lower eyelid can occur following BOTOX® injection(s).
- Blindness is extremely rare after BOTOX® injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. According to Allergan, the company that produces BOTOX®, over a period of 10 years of BOTOX® administration, complications of blurred vision, retinal vein occlusion, and glaucoma have been reported in three patients. The occurrence of eye problems appears to be very rare.
- The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to BOTOX® injection.
- Discomfort associated with BOTOX® injections is usually of a short duration.
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- There is the possibility of a poor or inadequate response from BOTOX® injection(s). Additional BOTOX® injections may be necessary. In some cases, lines are too engraved to be corrected with BOTOX® alone and may require other forms of treatment (fillers) or surgical procedures to improve skin wrinkles including those caused by muscle activity.
- As with all biologic products, allergic and systemic life-threatening anaphylactic reactions may occur. Allergic reactions may require additional treatment. Systemic anaphylactic reactions require immediate medical care.
- Infection is extremely rare after BOTOX® injection. Should an infection occur, additional treatment including antibiotics may be necessary.
- Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to BOTOX® injections. Future surgery or other treatments may be necessary. BOTOX® injection does not arrest the aging process or produce permanent tightening of the eyelid region. Continuing treatments are necessary in order to maintain the effect of BOTOX® over time.
- Animal reproduction studies have not been performed to determine if BOTOX® could produce fetal harm. It is not known if BOTOX® can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BOTOX® treatments.
- Local or systemic skin rash, itching, and swelling may rarely occur following BOTOX® injection.
- Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk of clinically significant side effects from BOTOX®.
- BOTOX® has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of off-label BOTOX® treatment for migraine headaches and other medical disorders may be variable and improvement may not occur following BOTOX® treatments.

CONSENT FOR TREATMENT

I hereby authorize Dr. Jaccoma or Dr. Lazos to perform the following treatment: **BOTOX® INJECTIONS FOR COSMETIC PURPOSES**. I have read the above information regarding Botox® Injections. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained. **I have discussed with Dr. Jaccoma or Dr. Lazos whether or not I have a history of cold sores and standard precautions have been taken if necessary.** I consent to having my photo taken for educational and medical purposes. The treatment and procedure has been explained to me in a way that I understand. All my questions and concerns have been addressed.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____