

## **CONSENT FOR BOTULINUMTOXIN A**

### **GENERAL INFORMATION**

The Botulina Type A Toxin (BOTOX) 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.

BOTOX has been approved to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder with the neck) and motor disorders of the facial nerve (VII cranial nerve). 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 crows feet wrinkles and neck bands may be treated in an "off-label" fashion. BOTOX has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

BOTOX injections are customized for every patient, depending on his or her particular needs. BOTOX cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups associated with facial expression. BOTOX injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

### **RISKS of BOTOX (Botulina Type A Toxin) Injections**

Although the majority of patients do not experience any complications, you should discuss the potential risks with your plastic surgeon to ensure that you understand the potential complications, limitations, and consequences of BOTOX injections. Additional information concerning BOTOX may be obtained from the package-insert sheets supplied by Allergan.

The risks include: Pain, bleeding, bruising, infection, skin irritation, allergic reaction, temporary eyelid droop (ptosis), asymmetry, unsatisfactory results, migration of product, temporary eyelid disorders, injury to deeper structure, and blindness.

For more thorough explanation, see details below.

**Pain**- Discomfort associated with BOTOX injections is usually short duration.

**Bleeding and Bruising**- It is possible, though unusual, to have a bleeding episode from a BOTOX injection. Bruising in soft tissues may occur. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. If you have a history of bleeding concerns, do not take these for ten days before or after BOTOX injections.

**Infection**- Infection is extremely rare after BOTOX injection. Should an infection occur, additional treatment including antibiotics may be necessary.

**Skin Irritation**- Skin rash, itching, and swelling may rarely occur following BOTOX injection.

**Allergic Reactions**- As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

**Antibodies to BOTOX**- Presence of antibodies to BOTOX may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BOTOX is unknown.

**Asymmetry**- 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.

**Unsatisfactory Result-** There is the possibility of a poor or inadequate response from BOTOX injection. Additional BOTOX injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

**Migration of BOTOX-** 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).

**Drooping Eyelid (Ptosis) -** Muscles that raise the eyelid may be affected by BOTOX, should this material migrate downward from other injection areas.

**Double-Vision-** Double-vision may be produced if the BOTOX material migrates into the region of muscles that control movements of the eyeball.

**Eyelid Ectropion-** Abnormal looseness of the lower eyelid can occur following BOTOX injection.

**Corneal Exposure Problems-** 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 may be necessary.

**Dry Eye Problems-** Individuals who normally have dry eyes may be advised to use special caution in considering BOTOX injections around the lower eyelid region.

**Damage to Deeper Structures-** Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

**Blindness-** Blindness is extremely rare after BOTOX injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In 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.

**Neuromuscular Disorders-** 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.

**Migraine Headache Disorders-** BOTOX has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of BOTOX treatment for migraine headaches may be variable and improvement in this disorder may not occur following BOTOX treatments.

**Long-Term Effects-** Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss, weight gain, sun exposure, pregnancy, menopause, or other circumstances not related to BOTOX injections. BOTOX injection does not arrest the aging process or produce permanent tightening of the eyelid region. Future surgery or other treatments may be necessary.

**Pregnancy and Nursing Mothers-** 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.

**Drug Interactions-** The effect of BOTOX may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

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**Unknown Risks-** The long-term effect of BOTOX on tissue is unknown. The risk and consequences of accidental intravascular injection of BOTOX is unknown and not predictable. There is the possibility of additional risk factors may be discovered.

**ALTERNATIVE TREATMENTS**

Improvement of skin wrinkles may be accomplished by other treatments or surgical procedures such as a blepharoplasty, face or brow lift when indicated. Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid. Minor skin wrinkling may be improved through chemical skin peels, lasers, injection of filling material, or other skin treatments.

**HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

**ADDITIONAL TREATMENT NECESSARY**

Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BOTOX injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

**FINANCIAL RESPONSIBILITIES**

The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs of medical treatment would be your responsibility should complications develop from BOTOX injections. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

**PHOTOGRAPHIC RELEASE CONSENT:**

I give permission to take photographs of my treatment areas for diagnostic purposes and to document for the medical record. I agree that these photographs are the property of the doctor's office, and I give my permission to use these photographs for teaching purposes, for use in scientific publications, books, journals, lectures, seminars and electronic media. It is understood that in any such publication I shall not be identified by name and that appropriate measures shall be made to protect my identity. I understand that I will not receive any compensation for use of my photos for scientific and teaching/educational purposes.

I CONSENT TO THE TREATMENT OF BOTULINUMTOXIN A AND I HAVE READ THE ABOVE LISTED ITEMS. I AM SATISFIED WITH THE INFORMED CONSENT PROCESS

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Patient or Person Authorized to Sign for Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date