



Consent Form: Botulinum Toxin Cosmetic Injection

Name: _____ DOB: _____ Date: _____

The cosmetic form of **botulinum toxin** is a popular nonsurgical injection that temporarily reduces or eliminates facial fine lines and wrinkles. The most commonly treated areas are frown lines, forehead creases, crow's feet near the eyes. Several other areas have been treated such as thick bands in the neck, thick jaw muscles, lip lines and gummy smiles.

Botulinum toxin is a purified substance that's derived from bacteria. Injections of botulinum toxin block the nerve signals to the muscle in which it was injected. Without a signal, the muscle is not able contract. The end result is diminished unwanted facial wrinkles or appearance. Commonly known types of botulinum toxin type A injections include Botulinum toxin, Dysport and Xeomin.

Botulinum toxin can be used to

- Smooth crow's feet, forehead furrows, frown lines, lip lines and bunny lines
- Diminish neck bands
- Improve the appearance of skin dimpling of the chin
- Lift the corners of the mouth
- Soften a square jaw line
- Correct a gummy smile

The FDA has approved the use of Botulinum toxin for the frown lines and crow's feet, while Dysport and Xeomin are approved for frown lines only. All other uses are considered "off label."

RISKS OF BOTULINUM TYPE A TOXIN INJECTIONS

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your provider to make sure you understand risks, potential complications, limitations, and consequences of botulinum toxin injections.

Incomplete Block:

It is possible to not experience a complete block of desired muscles. Additional injections to reach the desired level of block can be performed until the goal is achieved.

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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 the botulinum toxin injection.

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

Pain: Discomfort associated with botulinum toxin injections is usually of short duration.

Migration of botulinum toxin: Botulinum toxin may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. Botulinum toxin has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).

Bleeding and Bruising: It is possible, though unusual, to have a bleeding episode from a botulinum toxin injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper botulinum toxin injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. 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. Do not take these for ten days before or after botulinum toxin injections.

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.

Corneal Exposure Problems: Some patients experience difficulties closing their eyelids after botulinum toxin 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.

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

Dry Eye Problems: Individuals who normally have dry eyes may be advised to use special caution in considering botulinum toxin injections around the eyelid region.

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

Eyelid Ectropion: Abnormal looseness of the lower eyelid can occur following botulinum toxin injection.

Other Eye Disorders: Functional and irritative disorders of eye structures may rarely occur following botulinum toxin injections.

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Blindness: Blindness is extremely rare after botulinum toxin injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In a period of 10 years of botulinum toxin 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.

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

Antibodies to botulinum toxin: Presence of antibodies to BOTULINUM TOXIN may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BOTULINUM TOXIN is unknown.

Infection: Infection is extremely rare after botulinum toxin injection. Should an infection occur, additional treatment including antibiotics may be necessary.

Skin Disorders: Skin rash, itching, and swelling may rarely occur following botulinum toxin injection.

Neuromuscular Disorders: Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, and motor neuropathies) may be at greater risk of clinically significant side effects from botulinum toxin.

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

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

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 botulinum toxin injections. Botulinum toxin 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 botulinum toxin could produce fetal harm. It is not known if botulinum toxin can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive botulinum toxin treatments.

Drug Interactions: The effect of botulinum toxin may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

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