



Informed Consent

Botulina Toxins – Botox®, Dysport, Xeomin Neurotoxins

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about Botulina Toxin A (BTA)-BOTOX®, Dysport, and Xeomin- injections, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent treatment as proposed by a Silk, A Medical Spa professional +10. and agreed upon by you.

GENERAL INFORMATION

Clostridia botulina bacteria produce a class of chemical compounds known as “toxins”. The Botulina Toxin A is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary weakness (chemo denervation) of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle weakness lasts 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 as of April 2002, it has been FDA-approved for the cosmetic treatment of wrinkles between the brows caused by specific muscle groups. Other areas of the face and body such as crow’s 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.

BTA injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region, forehead, and neck. BTA cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. BTA injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the skin wrinkles by any means. Improvement of skin wrinkles may be accomplished by other treatments or alternative types of surgery 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 such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion). Minor skin wrinkling may be improved through chemical skin peels, lasers, injection of fillers or fat, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

INHERENT RISKS OF BTA 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 surgical 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 plastic surgeon to make sure you understand risks, potential complications, limitations, and consequences of BTA injections. Additional information concerning BTA may be obtained from the package-insert sheets supplied by Allergan.

SPECIFIC RISKS OF BOTOX (BOTULINA TYPE A TOXIN) INJECTIONS

Incomplete Result:

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

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 BTA injection.

Drooping Eyelid (Ptosis):

Muscles that raise the eyelid may be affected by BTA, should this material migrate downward from other injection areas. Should this problem occur, it is temporary and additional treatments such as eye drops may be necessary.

Pain:

Discomfort associated with BTA injections is usually of short duration.

Migration of BTA:

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

Bleeding and Bruising:

It is possible, though unusual, to have a bleeding episode from a BTA injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BTA injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, you 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 BTA injections. If you are taking these medications, please inform your surgeon prior to proceeding.

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 BTA 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 BTA on tissue is unknown. The risk and consequences of accidental intravascular injection of BTA 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 BOTOX injections around the eyelid region.

Double-Vision:

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

Eyelid Ectropion:

Abnormal looseness of the lower eyelid can occur following BTA injection.

Other Eye Disorders:

Functional and irritive disorders of eye structures may rarely occur following BTA injections.

Blindness:

Blindness is extremely rare after BTA 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.

Allergic Reactions:

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

Antibodies to BTA:

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

Infection:

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

Skin Disorders:

Skin rash, itching, and swelling may rarely occur following BTA 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 BTA.

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 BTA treatment for migraine headaches may be variable and improvement in this disorder may not occur following BTA treatments.

Unsatisfactory Result:

There is the possibility of a poor or inadequate response from BTA injection. Additional BTA injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity. Unsatisfactory results may NOT improve with each additional treatment.

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 BTA injections. BTA injection does not stop the aging process or produce permanent tightening of skin. Future surgery or other treatments may be necessary.

Pregnancy and Nursing Mothers:

Animal reproduction studies have not been performed to determine if BTA could produce fetal harm. It is not known if BTA can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BTA treatments. Please inform your surgeon prior to proceeding if you are pregnant or think you could be or if you are nursing.

Drug Interactions:

The effect of BTA may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed procedure along with disclosure of risks and alternative forms of treatment(s), including a decision not to proceed with the procedure. This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your medical spa professional may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR BOTULIN TOXINS (BOTOX, DYSPORT, XEOMIN NEUROTOXINS)

1. I hereby authorize Silk, A Medical Spa to perform **Botulina Toxins Injection**.

I have received the following information sheet: **Botulina Toxins Injection**.

2. I understand what my medical spa professional can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

3. I consent to be photographed or televised before, during, and after the procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

4. I realize that not having the procedure is an option. I opt out of having this procedure _____.

8. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date/Time _____ Witness _____