



INFORMED CONSENT FOR INJECTION OF NEUROTOXINS (Botox®, Dysport®, Xeomin®, Daxxify®)

INSTRUCTIONS

This informed consent document has been prepared to help us inform you about “Toxin” injections, their risks, and alternative treatments. 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 for the procedure proposed.**

INTRODUCTION

Clostridium botulinum bacteria produce a chemical compound known as Botulinum Type A toxin. The Botulinum Type A Toxin (“Toxins”) 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 (chemo-denervation) of the muscle by preventing the transmission of nerve impulses to the muscle. The duration of muscle paralysis is generally three months. “Toxins” have been used to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), and motor disorders of the facial nerve (VII cranial nerve). It has been used in other “off-label” uses for the treatment of facial wrinkles and neck bands caused by specific muscle groups. This agent has also treated certain spastic muscle disorders in the neck and colorectal area. “Toxins” injections are customized for every client, depending on his/her particular needs. These can be performed in areas involving the eyelid region, forehead, and neck. “Toxins” cannot stop the process of aging. It can temporarily diminish the look of wrinkles caused by muscle groups. “Toxins” 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 browlift 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 filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

RISKS OF “TOXINS” (Botulinum Toxin Type A) 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 the potential benefit. Although the majority of clients do not experience the following complications, you should discuss each of them with your treating clinician to make sure you understand the risks, potential complications, and consequences of “Toxins” injections.

Bleeding – It is possible, though unusual, to have a bleeding episode from a “Toxins” injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper “Toxins” injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Do not take any aspirin or anti-inflammatory medications for seven days before “Toxins” injections, as this may contribute to a greater risk of a bleeding problem.

Infection – Infection is extremely rare after “Toxins” injection. Should an infection occur, additional treatment including antibiotics may be necessary.

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 clients experience difficulties closing their eyelids after “Toxins” 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 “Toxins” injections around the eyelid region.

Migration of “Toxins” – “Toxins” may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects.

Drooping Eyelid (Ptosis) – Muscles that raise the eyelid may be affected by “Toxins”, should this material migrate from injection areas.

Double-Vision – Double vision may be produced if the “Toxins” material migrates into the region of muscles that control movements of the eyeball.

Eyelid Ectropion – Abnormal looseness of the lower eyelid can occur following “Toxins” injection.

Other Eye Disorders – Functional and irritative disorders of eye structures may rarely occur following “Toxins” injections.

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 “Toxins” injection,

Pain – Discomfort associated with “Toxins” injections is usually short duration.

Skin disorders – Skin rash and swelling may rarely occur following “Toxins” injection.

Unknown risks – The long-term effect of “Toxins” on tissue is unknown. There is the possibility that additional risk factors may be discovered.

Unsatisfactory result – There is the possibility of a poor or inadequate response from the “Toxins” injection. Additional “Toxins” injections may be necessary. Surgical procedures or treatments or injections with filler materials may be needed to improve skin wrinkles including those caused by muscle activity.

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

Antibodies to “Toxins” – The presence of antibodies to “Toxins” may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to “Toxins is unknown.

Long-term effects – 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 “Toxins” injections. “Toxins” 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 “Toxins” could produce fetal harm. It is not known if “Toxins” can be excreted in human milk.

Blindness – Blindness is extremely rare after “Toxins” injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. The occurrence of this is not predictable.

Drug Interactions – The effect of “Toxins” may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Additional treatment may be necessary – There are many variable conditions in addition to risk and potential complications that may influence the long-term result of “Toxins” injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with “Toxins” injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

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.

FINANCIAL RESPONSIBILITIES

The cost of “Toxins” injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the “Toxins” material itself. If a follow-up visit is necessary additional units of “Toxins” may be purchased at the same price per unit as the initial visit. It is unlikely that “Toxins” injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from “Toxins injections.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). This informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most clients in most circumstances. However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. You may be provided with additional or different information which is based on all of the facts pertaining to your particular case and the 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.

CONSENT FOR INJECTION OF “TOXINS”

1. I, _____ hereby authorize doctors and such assistants or appropriately trained, licensed, and credentialed medical staff members under his supervision as have been selected to perform the following procedure or treatment: **Injection of “Toxins” (Botulinum Toxin Type A) for treatment of facial rhytids.**
2. I recognize that during the course of the medical treatment, unforeseen conditions may necessitate different procedures than those above. I, therefore, authorize the above physician and assistants or designee to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure begins.
3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
4. I acknowledge that a follow-up treatment within 2 weeks may be necessary, and additional units of “Toxins may be purchased at the same price per unit as the initial visit.
5. For the purposes of medical record-keeping, clinical reporting, and marketing, I consent to the taking and publishing of photographs.
6. For purposes of advancing medical education, I consent to the admittance of observers.
7. I authorize the release of my Social Security number to appropriate agencies for legal reporting, if applicable.
8. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THE RISKS OF THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND UNDERSTAND THE INFORMED CONSENT FOR INJECTION OF “TOXINS”, THE ABOVE LISTED ITEMS, AND I AM SATISFIED WITH THE EXPLANATION.

Client Signature

Date

Witness

Date