

INFORMED CONSENT: NEUROTOXIN INJECTIONS

(Allergan BOTOX® Botulina Toxin Type A; Merz Xeomin® Incobotulinumtoxin A)

This is an informed-consent document which has been prepared to help your physician inform you concerning Neurotoxin (ALLERGAN BOTOX® BOTULINA TOXIN TYPE A; MERZ XEOMIN® Incobotulinumtoxin A) injections, its 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 this procedure as proposed by your physician or nurse injector.

INTRODUCTION

Clostridia botulina bacteria produce a class of chemical compounds known as “toxins”. The Neurotoxin (ALLERGAN BOTOX® BOTULINA TOXIN TYPE A; MERZ XEOMIN® Incobotulinumtoxin 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 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 with standard dosing. Continuing treatments are necessary in order to maintain the effect of Neurotoxins over time.

Neurotoxins have 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 may also be treated in an “off-label” fashion. Neurotoxins have also been used “off-label” to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

Neurotoxin 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. Neurotoxins cannot stop the process of aging. It can, however, temporarily diminish the look of wrinkles caused by muscle groups. Neurotoxin 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. 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 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 NEUROTOXIN 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 should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of Neurotoxin injections.

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BLEEDING- It is possible, though unusual, to have a bleeding episode from a Neurotoxin injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper Neurotoxin 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 Neurotoxin injections, as this may contribute to a greater risk of a bleeding problem.

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 Neurotoxin 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 Neurotoxin injections around the eyelid region.

MIGRATION OF Neurotoxin - Neurotoxin may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. Neurotoxin 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 Neurotoxin, should this material migrate downward from other injection areas.

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

EYELID ECTROPION- Abnormal looseness of the lower eyelid can occur following Neurotoxin injection(s).

OTHER EYE DISORDERS- Functional and irritative disorders of eye structures may rarely occur following Neurotoxin injections.

BLINDNESS- Blindness is extremely rare after Neurotoxin injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. According to Allergan, the company that produces Neurotoxin, over a period of 10 years of Neurotoxin 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.

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 Neurotoxin.

PAIN- Discomfort associated with Neurotoxin injections is usually of a short duration.

UNSATISFACTORY RESULT- There is the possibility of a poor or inadequate response from Neurotoxin injection(s). Additional Neurotoxin injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

ALLERGIC REACTIONS- 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.

ANTIBODIES TO Neurotoxin - Presence of antibodies to Neurotoxin may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to Neurotoxin is unknown.

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

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 Neurotoxin. Future surgery or other treatments may be necessary. Neurotoxin 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 Neurotoxin over time.

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PREGNANCY AND NURSING MOTHERS- Animal reproduction studies have not been performed to determine if Neurotoxin could produce fetal harm. It is not known if Neurotoxin can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Neurotoxin treatments.

DRUG INTERACTIONS- The effect of Neurotoxin may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

SKIN DISORDERS- Local or systemic skin rash, itching, and swelling may rarely occur following Neurotoxin injection.

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 Neurotoxin.

MIGRAINE HEADACHE AND OTHER MEDICAL DISORDERS- Neurotoxin has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of off-label Neurotoxin treatment for migraine headaches and other medical disorders may be variable and improvement may not occur following Neurotoxin treatments.

UNKNOWN RISKS- The long term effect of Neurotoxin on tissue is unknown. The risk and consequences of accidental intravascular injection of Neurotoxin is unknown and not predictable. There is the possibility that additional risk factors may be discovered.

ADDITIONAL TREATMENTS MAY BE NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long term result of Neurotoxin injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Neurotoxin 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 RESPONSIBILITY

The cost of Neurotoxin 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 Neurotoxin material itself. It is unlikely that Neurotoxin 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 Neurotoxin injections.

I understand that my treatments require payment at the time of service and the prices and fee structure for treatments have been explained to me.

There are no refunds on treatments or on treatments paid for in advance. Initial: _____

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). 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 physician may provide you 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 following consent.

Initial: _____

CONSENT FOR PROCEDURE OR TREATMENT

1. I hereby authorize Dr. John Bass, Lisa Shea RN, and / or a designated licensed practitioner to perform Neurotoxin injections.
2. I have read the Neurotoxin Injection Informed Consent information sheet.
3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained and that there are no refunds for treatments.
4. I consent to photographing the operation(s) or 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.
5. It is my responsibility to notify Dr. John Bass, Lisa Shea RN, and / or a designated licensed practitioner if I have had any other skincare treatments within the last two weeks, or am planning on having in the following two weeks.
6. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
7. 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 as described above. I am satisfied with the explanation.

Patient's Name (Printed): _____

Signature: _____ Date: _____

Staff Signature: _____ Date: _____