INFORMED CONSENT – XEOMIN® INJECTION

INSTRUCTIONS

This is an informed-consent document which has been prepared to help your physician inform you concerning XEOMIN® (incobotulinumtoxin A) injection, 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 and agreed upon by you.

GENERAL INFORMATION

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The incobotulinumtoxin A Toxin (XEOMIN) 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.

XEOMIN has been FDA approved to treat certain conditions including cervical dystonia and blepharospasm. Cosmetic FDA-approved indications now include the glabellar lines.

XEOMIN injections are customized for every patient, depending on his or her particular needs. XEOMIN cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. XEOMIN 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 filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

RISKS of XEOMIN 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 cosmetic 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 physician to make sure you understand risks, potential complications, limitations, and consequences of XEOMIN injections. Additional information concerning XEOMIN may be obtained from the package-insert sheets supplied by Merz Aesthetics.

Bleeding and Bruising- It is possible, though unusual, to have a bleeding episode from a XEOMIN injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper XEOMIN 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 XEOMIN 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.

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Corneal Exposure Problems- Some patients experience difficulties closing their eyelids after XEOMIN 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 XEOMIN injections around the eyelid region.

Migration of XEOMIN- A black-box warning is listed in the package insert of XEOMIN cosmetic. This indicates that the effects of XEOMIN may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. They have been reported to occur hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. These reports are more common in patients who have an underlying condition that would predispose them to these symptoms.

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

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

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

Other Eye Disorders- Functional and irritative disorders of eye structures may rarely occur following XEOMIN injections.

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

Pain- Discomfort associated with XEOMIN injections is usually short duration.

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

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

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

Skin Disorders- Skin rash, itching, and swelling may rarely occur following XEOMIN 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 XEOMIN.

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

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

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

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

HEALTH INSURANCE

Most health insurance companies exclude coverage for 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

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of XEOMIN injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with XEOMIN 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 cost of XEOMIN 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 XEOMIN material itself. It is unlikely that XEOMIN injections to treat cosmetic problems would be covered by your health insurance. 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 XEOMIN injections.

In signing the consent for this procedure, you acknowledge that your 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.

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.

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DISCLAIMER (continued)
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 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.

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PATIENT INFORMATION FOR XEOMIN® COSMETIC

Prior to XEOMIN injection(s):

- If you are on a blood-thinner including aspirin or baby aspirin this must be discussed with your physician one week prior to treatment. The risk of bruising and bleeding is significantly higher in patients that have blood-thinners in their system.

After XEOMIN injection(s):

- Do not lie down for four hours after treatment.
- Do not massage the treated area. This can cause XEOMIN to spread to the other muscles increasing the risks of complications.
- Exercise the muscles every 15 minutes for one hour after the treatment.
- XEOMIN cosmetic maximum results are usually achieved at about 10 days after treatment. Occasionally, a series of treatments are needed to receive the desires results. There will be a charge incurred for each treatment required to achieve those results. Injections can be repeated every 3-6 months.