

XEOMIN® INFORMED CONSENT

This is an informed-consent document which has been prepared to help your Medical Injector inform you concerning (IncobotulinumtoxinA) injection, its risks, likely effects and alternative treatments.

It is important that you read this information carefully and completely. Please sign the consent for this procedure as proposed by your Medical Injector and agreed upon by you, indicating that you have read the informed consent.

I, _____ authorize Medical Injector _____ to perform the following procedure: **Xeomin® Injection.**

INDICATIONS AND ALTERNATIVES

Xeomin® is a brand name for IncobotulinumtoxinA, which is processed and purified to produce a sterile product suitable for specific therapeutic uses. Xeomin® is an acetylcholine release inhibitor and neuromuscular blocking agent which produces a temporary paralysis of muscle by preventing transmission of nerve impulses to muscle, essentially blocking messages between muscles and the nerves that control them. This works to smooth the lines of animation on the face. The effects of Xeomin® become apparent in as little as 2-5 days after injection or as long as 10-14 days after injection and generally last for 3-4 months. The FDA has approved the use of Xeomin® to treat the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity.

While the FDA has not approved injections to improve the appearance of wrinkles in other areas of the face, medical injectors may perform these “off-label” procedures such as crows feet wrinkles. Subsequent alterations in face and eyelid appearance may occur as a result of aging, weight loss or weight gain, sun exposure, pregnancy, menopause or other circumstances not related to Xeomin® injections. Xeomin® injections do not arrest the aging process or produce permanent tightening of the eyelid region. There are alternatives to Xeomin®, including no treatment, lasers, chemical peels, filler injections, medicines or surgery (blepharoplasty, face or brow lift) on facial nerves and muscles.

SIDE EFFECTS AND COMPLICATIONS

Every procedure involves a certain amount of risk and possible complications associated with them. Although the majority of clients do not experience these complications you should discuss each of them with your medical injector to understand risks, potential complications, limitations and consequences.

Side effects and complications include but are not limited to:

1. Bruising, bleeding, redness, itching, swelling, discomfort or erythema (raised areas) at the injection site.
2. Allergic and systemic anaphylactic reactions may occur. Xeomin® is contraindicated in clients with a known hypersensitivity to the active substance botulinum toxin type A or to any of the components in the formulation such as human serum albumin. Hypersensitivity reactions have

been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea).

3. Under correction (not enough effect) or overcorrection (too much effect).
4. Facial asymmetry (one side looks different than the other).
5. Migration of Xeomin® from its original injection site to other areas which may lead to paralysis of a nearby muscle groups leading to: droopy eyelid, abnormal looseness of lower eyelid, double vision, inability to close eyelid, difficulty whistling, swallowing or drinking from a straw.
6. Treatment with Xeomin® and other botulinum toxin products can result in swallowing or breathing difficulties. Clients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. These reactions can occur within hours to weeks after injection with botulinum toxin. Seek immediate medical care if swallowing, speech or respiratory disorders arise.
7. Dry eye problems for individuals who normally have dry eyes may be advised to use special caution in considering Xeomin® injections around the eyelid region. Excessive bleeding around the eyeball or needle stick injury causing trauma to the eye or blindness. Corneal exposure resulting in difficulty closing the eyes may occur. Xeomin® may cause reduced blinking or effectiveness of blinking, and that I should seek immediate medical attention if eye pain or irritation occur following treatment. An inability to blink the eyelids normally may result in corneal exposure and has been associated with damage to the eye as impaired vision, or double vision, which is usually temporary. The reduced ability to blink has been associated with corneal ulcerations. These side effects can last for several weeks or longer.
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9. Generalized weakness.
10. Permanent loss of muscle tone with repeated injection.
11. Damage to deeper structures such as nerves and blood vessels during the course of injection which may be temporary or permanent.
12. Flu-like syndrome or respiratory infection.
13. Infection at treatment site is extremely rare and should that occur, antibiotics may be necessary.
14. Nausea or headache.
15. Development of antibodies to Xeomin® cosmetic (that effect duration or result of treatment).

16. Xeomin® contains human-derived albumin and carries a theoretic risk of virus transmission. There have been no reports of disease transmission through Xeomin®.

CONTRAINDICATIONS

You should not have Xeomin® if you are pregnant, nursing, allergic to albumin or cow's milk, have an infection, skin condition, or muscle weakness at the site of injection or have peripheral motor neuropathic disorders (Eaton-Lambert syndrome, Lou Gehrig's disease, or Myasthenia Gravis).

Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other herbs/homeopathic remedies may contribute to a greater risk of bleeding problem. Do not take these for ten days before or after Xeomin® injections.

I understand the above, and have had the risks, complications, benefits, and alternatives explained to me. No guarantees about results have been made.

CONSENT

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees should they be required. 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 may occur should complications develop from the injections and will also be your responsibility.

I agree to follow up with Body+Beauty Lab at the recommended intervals to monitor the effectiveness of the treatment, and to contact Body+Beauty Lab to advise of any change in my condition or any problem I may experience.

In signing this consent for this procedure, you acknowledge that you have read the informed consent and have been informed about its risks and consequences and accept responsibility for the clinical decisions that have been made, along with the financial costs of all treatments and future treatments. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I give my informed consent for Xeomin® injections today as well as future treatments as needed.

Client Signature _____ Date _____

Medical Injector Signature _____ Date _____