

# MERZ AESTHETICS™

## XEOMIN® (incobotulinumtoxinA) Treatment Patient Informed Consent Form

I, \_\_\_\_\_ understand that I will be injected with XEOMIN® (incobotulinumtoxinA) in the glabellar lines.

XEOMIN® is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

**Risks and complications** that may be associated with injection with XEOMIN® (incobotulinumtoxinA) include, but are not limited to:

1. **Headaches:** I understand that headaches are possible and usually last one day but may persist longer in a very small percentage of patients.
2. **Injection Site Bruising:** I understand that bruising in soft tissues is possible as a result of the needle puncture of the skin. Bruising can last for several hours, days, weeks, months and, in rare cases, the effect of bruising could be permanent.
3. **Facial Paresis (Eyelid Ptosis):** I understand that local weakness of the injected muscles is the expected pharmacological action of XEOMIN® and weakness of adjacent muscles may occur which may result in temporary eyelid "drooping."
4. **Injection Site Bruising, Pain, Swelling, Rash, Local Numbness:** I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.
5. **Eye Disorder:** I understand that injections of 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 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.
6. **Infection:** As with all transcutaneous procedures, I understand that injection of any material carries the risk of infection.
7. **Hypersensitivity:** XEOMIN® is contraindicated in patients 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).
8. **Swallowing and Breathing Difficulties:** I understand that treatment with XEOMIN® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients 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.
9. **Pregnancy and Nursing:** There are no adequate and well-controlled studies of XEOMIN® in pregnant or nursing women.

**If you experience loss of strength, muscle weakness, blurred vision, or drooping eyelids occur, avoid driving a car or engaging in other potentially hazardous activities.**

No studies of interactions of XEOMIN® with other drugs or substances or implants have been conducted.

**Patient Acknowledgements:**

This above list is not meant to be inclusive of all possible risks associated with XEOMIN® (incobotulinumtoxinA) as there are both known and unknown side effects and complications associated with any medication. I understand that medical attention may be required to resolve complications associated with my injection.

**I confirm that I have received and reviewed the XEOMIN® Medication Guide.** I confirm that I have discussed the potential risks and benefits of XEOMIN® with my doctor and that my doctor has satisfactorily answered all of my questions. I understand that there is no guarantee of any particular results of any treatment. I understand the results of treatment with XEOMIN® are temporary.

I acknowledge that I am not pregnant or possibly pregnant, lactating or nursing.

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. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the doctor, the person performing the XEOMIN® injection and the facility from liability associated with this procedure.

\_\_\_\_\_  
Patient Signature Date

\_\_\_\_\_  
Witness Signature Date

Witness Address: \_\_\_\_\_  
\_\_\_\_\_

**WARNING: DISTANT SPREAD OF TOXIN EFFECT**  
Postmarketing reports indicate that the effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

**Please see Patient Medication Guide (following pages).**