MERZ AESTHETICS™

Annie A. Barseghian MD Inc.
FAMILY MEDICINE

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 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.
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

Doctor: Annie A Barseghian MD

Doctor Signature: _____ Date: _____

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN (incobotulinumtoxinA) for injection, for intramuscular use, 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).

EM00454-01

Medication Guide
XEOMIN® (Zeo-min) (incobotulinumtoxinA)
for injection, for intramuscular use

Read this Medication Guide before you start receiving XEOMIN® and each time XEOMIN® is given to you. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information that I should know about XEOMIN®?

XEOMIN® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with XEOMIN®:

- **Problems with swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of XEOMIN®** if the muscles that you use to breathe and swallow become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with XEOMIN®.
- People with certain breathing problems may need to use muscles in their neck to help them breathe. These patients may be at greater risk for serious breathing problems with XEOMIN®.
- Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving XEOMIN® have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:
  - » loss of strength and muscle weakness all over the body
  - » double vision
  - » blurred vision and drooping eyelids
  - » hoarseness or change or loss of voice
  - » trouble saying words clearly
  - » loss of bladder control
  - » trouble breathing
  - » trouble swallowing

These symptoms can happen hours to weeks after you receive an injection of XEOMIN®.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving XEOMIN®?"

What is XEOMIN®?

XEOMIN® is a prescription medicine that is injected into muscles and used:

- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (BOTOX).
- to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults for a short period of time (temporary).

It is not known whether XEOMIN® is safe or effective in children.

Who should not take XEOMIN®?

Do not take XEOMIN® if you:

- are allergic to XEOMIN® or any of the ingredients in XEOMIN®. **See the end of thisMedication Guide for a list of ingredients in XEOMIN®.**
- had an allergic reaction to any other botulinum toxin products such as rimabotulinumtoxinB (MYOBLOC®), onabotulinumtoxinA (BOTOX®, BOTOX® COSMETIC), or abobotulinumtoxinA (DYSPORT®).
- have a skin infection at the planned injection site.

What should I tell my doctor before receiving XEOMIN®?

Before you take XEOMIN® tell your doctor about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). **See "What is the most important information I should know about XEOMIN®?"**
- have allergies to any botulinum toxin product
- have had any side effect from any other botulinum toxin in the past
- have a breathing problem, such as asthma or emphysema
- have a history of swallowing problems or inhaling food or fluid into your lungs (aspiration)
- have bleeding problems
- have drooping eyelids
- have plans to have surgery
- have had surgery on your face
- are pregnant or plan to become pregnant. It is not known if XEOMIN® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XEOMIN® passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.

Using XEOMIN® with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received XEOMIN® in the past.**

Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months

- have received injections of botulinum toxin such as rimabotulinumtoxinB (MYOBLOC®), onabotulinumtoxinA (BOTOX®, BOTOX® COSMETIC) and abobotulinumtoxinA (DYSPORT®) in the past. Be sure your doctor knows exactly which product you received. The dose of XEOMIN® may be different from other botulinum toxin products that you have received.
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine
- take a blood thinner medicine

Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How will I receive XEOMIN®?

- XEOMIN® is a shot (injection) that your doctor will give you.
- XEOMIN® is injected into your affected muscles.
- Your doctor may change your dose of XEOMIN® until you and your doctor find the best dose for you.

What should I avoid while receiving XEOMIN®?

XEOMIN® may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking XEOMIN®. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.** See "What is the most important information I should know about XEOMIN®?"

What are the possible side effects of XEOMIN®?

XEOMIN® can cause serious side effects. See "What is the most important information I should know about XEOMIN®?"

- **XEOMIN may cause other serious side effects including** allergic reactions. Symptoms of an allergic reaction to XEOMIN® may include: itching, rash, redness, swelling, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint.

The most common side effects of XEOMIN® include:

- dry mouth
- discomfort or pain at the injection site
- tiredness
- headache
- neck pain
- muscle weakness
- eye problems, including: double vision, blurred vision, drooping eyelids, swelling of your eyelids, and dry eyes. Reduced blinking can also occur. Tell your doctor or get medical help right away if you have eye pain or irritation following treatment.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of XEOMIN®. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1- 800-FDA-1088.

General information about XEOMIN®

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

XEOMIN® should not be used for a condition for which it was not prescribed.

This Medication Guide summarizes the most important information about XEOMIN®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about XEOMIN® that is written for healthcare professionals.

For more information go to www.Xeomin.com or call 888-493-6646.

What are the ingredients in XEOMIN®?

Active ingredient: incobotulinumtoxinA

Inactive ingredients: human albumin and sucrose

Distributed by:
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and

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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