

XEOMIN® (incobotulinumtoxinA) IMPORTANT CONSUMER SAFETY INFORMATION

Read the Medication Guide before you start receiving XEOMIN® (Zeo-min) and each time XEOMIN® is given to you as there may be new information. The risk information provided here is not comprehensive. To learn more:

- Talk to your health care provider or pharmacist
- Visit www.xeominaesthetic.com to obtain the FDA-approved product labeling
- Call 1-866-862-1211

Uses XEOMIN® is a prescription medicine that is injected into muscles and used 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 if XEOMIN is safe and effective in children under 18 years of age.

Warnings

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 anytime (hours to weeks) after treatment with XEOMIN®:

- **Problems with swallowing, speaking, or breathing can happen within hours to weeks after an injection of XEOMIN®** if the muscles that you use to breathe and swallow become weak. 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 and may be at greater risk for serious breathing problems with XEOMIN®.
- Swallowing problems may last for several months, and during that time you 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.

Do not use XEOMIN® if you are allergic to XEOMIN® or any of the ingredients in XEOMIN® (see the end of this 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®) or have a skin infection at the planned injection site.

Before receiving XEOMIN®, tell your doctor about all of 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)
- 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 of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. **Talk to your doctor before you take any new medicines after you receive XEOMIN.**

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

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.

Possible Side Effects

XEOMIN® can cause serious side effects that can be life threatening including

Headache was the most common side effect of XEOMIN® for treatment of glabellar lines. Other possible side effects include:

- dry mouth
- discomfort or pain at the injection site
- tiredness
- 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.

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. **See "Warnings."**

The most common side effect of XEOMIN in people with glabellar lines include:

- headache

These are not all the possible side effects of XEOMIN®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of XEOMIN®

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about XEOMIN® that is written for health professionals.

Active Ingredient: botulinum toxin type A