

XEOMIN® FAQs

WHAT IS XEOMIN®?

XEOMIN® (incobotulinumtoxinA) is a prescription medication used to temporarily improve the appearance of moderate to severe frown lines between the eyebrows (glabellar lines) in adults. XEOMIN® contains botulinum toxin type A, a protein purified from the bacterium Clostridium botulinum.

HOW DOES XEOMIN® WORK?

When you squint or frown, the muscles between your brows contract, causing the skin to furrow and fold. Over time, as your skin ages and loses some of its elasticity, these repeated contractions can cause persistent frown lines.

Botulinum toxin type A – the active ingredient in XEOMIN® – acts on nerve endings in muscles to prevent muscle fibers from contracting. By reducing these contractions, XEOMIN® can temporarily reduce the lines on your forehead between your brows.

IS XEOMIN® PROVEN?

XEOMIN® was proven effective in two randomized, double-blind, multicenter, placebo-controlled clinical trials of 547 healthy, adult patients. The average age of patients in the study was 46 years. Patients received 20 Units of XEOMIN® and were classified as responders if they had a 2-grade improvement on a 4-point scale as assessed by the physician and patient. Using these criteria, treatment success was higher with XEOMIN® than placebo on Day 30 in both studies (60% and 48% vs. 0% for placebo in both studies). Based on these trials, XEOMIN® received FDA approval for aesthetic use in

HOW DO I KNOW IF XEOMIN® IS RIGHT FOR ME?

If you are an adult with moderate to severe glabellar lines, XEOMIN® may be right for you. Talk to your doctor to discuss the benefits and risks of treatment.

Do not take XEOMIN® if you are allergic to botulinum toxin or any of the other ingredients in XEOMIN®. You should also not take XEOMIN® if you have had an allergic reaction to any other botulinum toxin product or have a skin infection at the planned injection site.

WHAT SHOULD I TELL MY DOCTOR BEFORE TREATMENT?

Before receiving treatment with XEOMIN® you should tell your doctor about all of your medical conditions, including whether you have a disease that affects your muscles and nerves, have allergies to any botulinum toxin product, or have experienced any side effect from any other botulinum toxin in the past.

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

Especially tell your doctor if you have received any other botulinum toxin product in the last four months or in the past. Be sure your doctor knows exactly which product(s) you received and when you received them.

PLEASE SEE THE ACCOMPANYING XEOMIN MEDICATION GUIDE AND FULL PRESCRIBING INFORMATION FOR A COMPLETE DISCUSSION OF THE RISKS AND BENEFITS OF TREATMENT.

WHAT CAN I EXPECT DURING TREATMENT?

During treatment, which usually takes about 10-20 minutes, your doctor will inject XEOMIN® into the muscles in your forehead that cause frown lines between your brows. No anesthesia is required; however, your physician may use a topical anesthetic or cold pack to reduce any discomfort.

WHEN CAN I EXPECT TO SEE RESULTS?

In clinical trials, some patients observed visible smoothing as early as 3-4 days after injection. The median first onset of effect was less than a week. The maximum effect typically occurs at 30 days. The typical duration of effect is up to 3 months, but may last significantly longer or shorter in individual patients.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF XEOMIN®?

XEOMIN® may cause 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 seek medical help right away if you have wheezing, experience other asthma symptoms, or if you become dizzy or faint.

In clinical trials of XEOMIN® for the treatment of frown lines between the brows, headache was the most common side

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.

Tell your doctor if you have any side effect that bothers you or that does not subside. These are not all of the possible side effects of XEOMIN®. For more information, see the Important Safety Information on the back cover, Medication Guide and Full Prescribing Information, or ask your doctor.

PLEASE CLICK HERE FOR THE ACCOMPANYING XEOMIN® MEDICATION GUIDE FOR A COMPLETE DISCUSSION OF THE RISKS AND BENEFITS OF TREATMENT.

PLEASE SEE IMPORTANT SAFETY INFORMATION BELOW.

abobotulinumtoxinA (Dysport®); have a skin infection at the planned injection site.

INDICATIONS AND USAGE XEOMIN (incobotulinumtoxinA) for injection, for intramuscular use, is a prescription medication that is injected

into facial muscles for the temporary improvement in the appearance of moderate to severe glabellar lines (frown lines) in adult patients.

IMPORTANT SAFETY INFORMATION 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 any time (hours to weeks) after treatment with XEOMIN: • Problems with swallowing, speaking, or breathing can happen after an injection of XEOMIN if the muscles that you

- use to breathe and swallow become weak. If these problems are severe, you could die. 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. Do not take XEOMIN if you: are allergic to XEOMIN or any of the ingredients in XEOMIN; had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (Myobloc®), onabotulinumtoxinA (Botox®, Botox® Cosmetic), or

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), as you may be at increased risk of serious side effects including difficulty swallowing or breathing. Tell your doctor if you have: had any side effect from any other botulinum toxin in the past; breathing problems such as asthma or emphysema; a history of swallowing problems or inhaling food or fluid into your lungs (aspiration); bleeding problems; drooping eyelids; plans to have surgery; had surgery on your face. Also tell your doctor if you 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 products. 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 or 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. Tell your doctor if you: 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. 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.

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.

Headache was the most common side effect of XEOMIN for treatment of glabellar lines. Other side effects of XEOMIN include: dry mouth, discomfort or pain at the injection site, tiredness, neck pain, muscle weakness, and 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Full Prescribing Information and Medication Guide for more information.

FM00743-00