

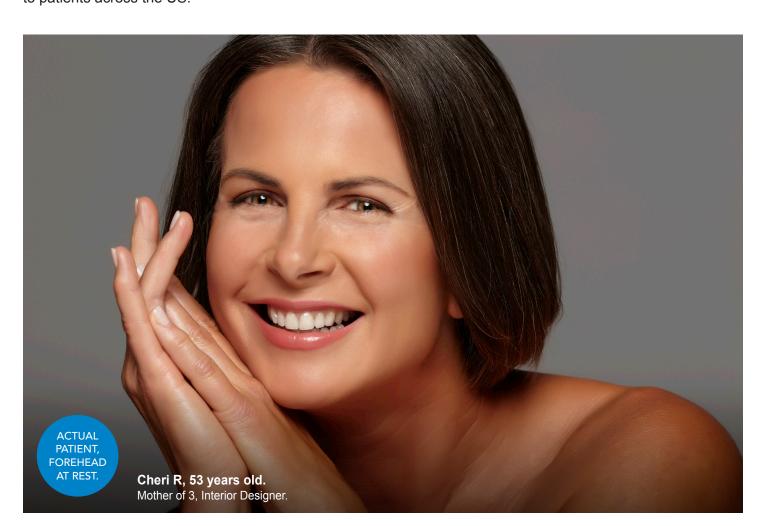
XEOMIN®

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.

Botulinum toxin type A 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.

XEOMIN® was approved by the US Food and Drug Administration (FDA) in July 2011. It is now widely available to patients across the US.



*Individual results may vary.

The typical duration of effect is up to 3 months but may last significantly longer or shorter in individual patients. In studies, XEOMIN® treated subjects ranged from 24 to 74 years of age with a mean age of 46.

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

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 <u>Full Prescribing Information</u> and <u>Medication Guide</u> for more information.