

APPENDIX 2: MEDICATION GUIDE

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

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®).

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 this Medication 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

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