



Merz Announces Nationwide Availability of New 200-Unit Vial of Xeomin®

New Vial Size Supports Adult Upper Limb Spasticity Indication

Frankfurt / Raleigh, N.C., USA, March 8, 2016 – Merz North America (U.S. affiliate of the global Merz Pharma Group), today announced the nationwide availability of [Xeomin® \(incobotulinumtoxinA\)](#) in a 200-unit single-dose vial. This new dosage size supports the dosing associated with the [recently approved adult upper limb spasticity indication](#) for Xeomin® (incobotulinumtoxinA). Xeomin® (incobotulinumtoxinA) is now available to healthcare providers in the US in three single-dose vial sizes: 50 unit, 100 unit and 200 unit, with the same price per toxin unit for all three sizes. Each vial size has a different color label, stopper and top to promote ease of use.

In particular, the new 200 unit vial of Xeomin® (incobotulinumtoxinA) offers convenience for treating adult patients with movement disorders such as upper limb spasticity and cervical dystonia. Additionally, Xeomin® (incobotulinumtoxinA) does not require refrigeration prior to reconstitution and unopened vials can be shipped and stored at room temperature for up to 36 months, offering flexible storage options for healthcare practices.

“It is our hope that the availability of multiple vial options for Xeomin® (incobotulinumtoxinA) may minimize dosing waste and reduce patient out-of-pocket costs,” said Glenn Block, Vice President and US Head of Merz Neurosciences. “The release of our 200-unit single dose vial of Xeomin® (incobotulinumtoxinA) represents Merz’s ongoing commitment to improving the experience of movement disorder patients and physicians.”

Xeomin® (incobotulinumtoxinA) is approved by the U.S. FDA for the treatment of adults with upper limb spasticity and cervical dystonia and to treat blepharospasm in adults who have had prior treatment with onabotulinumtoxinA (Botox®). Today, Xeomin® (incobotulinumtoxinA) is available in 49 countries across the globe. Over one million patients worldwide have been treated with Xeomin® (incobotulinumtoxinA)¹.

About Xeomin® (incobotulinumtoxinA)

Xeomin® (incobotulinumtoxinA) is a prescription medicine that is injected into muscles and used to treat increased muscle stiffness in the arm of adults with upper limb spasticity, the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults, and to treat abnormal spasm

Merz Pharma GmbH & Co. KGaA
Katja Marx
Corporate Communications
Eckenheimer Landstraße 100
D-60318 Frankfurt am Main
+49 69 1503-1176
katja.marx@merz.de

www.merz.com

¹ Data on file

of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (Botox®).

XEOMIN® 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.xeomin.com to obtain the FDA-approved product labeling
- Call 1-888-4-XEOMIN

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

- increased muscle stiffness in the arm of adults with upper limb spasticity
- abnormal head position and neck pain in adults with cervical dystonia (CD)
- 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.

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 week) 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 problems could make it unsafe for you to drive a car or do other dangerous activities.

Do not take 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 product such as rimabotulinumtoxinB (Myobloc®), onabotulinumtoxinA (Botox®, Botox® Cosmetic), or abobotulinumtoxinA (Dysport®) or have a skin infection at the planned injection site.

Ask a doctor before use 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 your medical conditions and all of the medicines you take, including prescription and over-the-counter 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.

Possible Side Effects

XEOMIN[®] can cause serious side effects that can be life threatening. See “Warnings.”

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.

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, dizziness or feeling faint. Tell your doctor or get medical help right away if you have wheezing or asthma symptoms, or if you get dizzy or faint.

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.

Directions

- 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.

General information about the safe and effective use of XEOMIN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not

use XEOMIN for a condition for which it was not prescribed. Do not give XEOMIN to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about XEOMIN that is written for health professionals.

Active Ingredient: incobotulinumtoxinA

Inactive Ingredients: human albumin and sucrose

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For more information, please see XEOMIN full [Prescribing Information](#) and [Medication Guide](#).

Corporate Contact:

Merz Pharmaceuticals GmbH & Co. KGaA
Corporate Communications
Katja Marx
Eckenheimer Landstraße 100
60318 Frankfurt am Main
Tel. +49 69 1503-1176
E-Mail: katja.marx@merz.de