



**MERZ NORTH AMERICA ANNOUNCES FDA APPROVAL  
OF XEOMIN<sup>®</sup> (incobotulinumtoxinA) FOR  
TREATMENT OF ADULT UPPER LIMB SPASTICITY**

RALEIGH, N.C. – DECEMBER 23, 2015 – BUSINESS WIRE – [Merz North America](#), U.S. affiliate of the global Merz Pharma Group, announces that [Xeomin<sup>®</sup> \(incobotulinumtoxinA\)](#) has received U.S. FDA approval for the treatment of upper limb spasticity (ULS) in adult patients. In clinical studies, treatment with Xeomin<sup>®</sup> (incobotulinumtoxinA) for adult ULS resulted in statistically and clinically significant improvements in muscle tone, with a safety profile similar to that observed for other Xeomin<sup>®</sup> (incobotulinumtoxinA) indications.

“We know that each patient has unique needs, and this new indication for Xeomin<sup>®</sup> (incobotulinumtoxinA) is a result of our long-term commitment to serving individuals living with movement disorders and spasticity,” said Glenn Block, Vice President and Head – US Neurosciences for Merz North America. “We look forward to supporting the launch of Xeomin<sup>®</sup> for adult upper-limb spasticity with forward-thinking strategies in product support, clinical education, and patient advocacy and engagement.”

Xeomin<sup>®</sup> (incobotulinumtoxinA) was first approved by the U.S. FDA in August 2010 for the treatment of adults with cervical dystonia and blepharospasm. Today, Xeomin<sup>®</sup> (incobotulinumtoxinA) is available in 43 countries across the globe. Over one million patients worldwide have been treated with Xeomin<sup>®</sup> (incobotulinumtoxinA)<sup>1</sup>.

“In multiple well-controlled clinical trials, treatment of adult ULS with Xeomin<sup>®</sup> (incobotulinumtoxinA) resulted in significant improvements in muscle tone,” said [David M. Simpson, MD, FAAN](#), Professor of Neurology at The Icahn School of Medicine at Mount Sinai, Department of Neurology. “The addition of this effective treatment option for adult ULS means that U.S. physicians now have greater flexibility in selecting a neurotoxin therapy that meets the needs of their individual patients.”

Dr. David M. Simpson is Director of the Neuromuscular Diseases Division and Clinical Neurophysiology Laboratories at The Icahn School of Medicine at Mount Sinai. Dr. Simpson is a member of the American Neurological Association and the American Pain Society. He is a Fellow of the American Academy of Neurology and the American Academy of Neuromuscular and Electrodiagnostic Medicine.

“Merz North America remains dedicated to pursuing strategic, targeted research and development programs in the neurosciences space, with the ultimate goal of

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<sup>1</sup> Data on file

providing meaningful treatment options for movement disorder and spasticity patients,” said David Dobrowski, Vice President and Head of Research and Development for Merz North America.

The safety and efficacy of Xeomin<sup>®</sup> (incobotulinumtoxinA) in the treatment of adult upper limb spasticity was evaluated in multiple Phase III clinical studies in more than 400 patients with ULS. The approval of Xeomin<sup>®</sup> (incobotulinumtoxinA) for the treatment of adult ULS is based on results of a randomized, multicenter, placebo-controlled trial showing significant improvements in two co-primary outcome parameters: muscle tone (Ashworth Scale score) change from baseline of the Primary Target Clinical Pattern (PTCP) and the Investigator’s Global Impression of Change of the subject’s upper limb spasticity [due to treatment] at Week 4. Both showed statistical significance, with  $p < 0.001$  and  $p = 0.003$  respectively. The trial also met a key secondary outcome measure, in which subjects with an improvement  $\geq 1$  on the Ashworth Scale at Week 4 were classified as responders ( $p < 0.001$ ). Treatment related adverse events were reported for 3.8% and 1.9% of subjects treated with Xeomin<sup>®</sup> (incobotulinumtoxinA) and placebo, respectively. The most commonly observed adverse reactions (incidence  $\geq 2\%$  of patients and greater than placebo) for Xeomin<sup>®</sup> were seizure (3%), nasopharyngitis (2%), dry mouth (2%), and upper respiratory tract infection (2%).

#### **About XEOMIN<sup>®</sup> (incobotulinumtoxinA)**

Xeomin<sup>®</sup> (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 of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (Botox<sup>®</sup>).

#### **About Merz Neurosciences**

Merz Neurosciences is a division of Merz North America, a specialty healthcare company that is dedicated to delivering a better total experience in aesthetics, dermatology and neurosciences. By working side by side with physicians and patients, Merz Neurosciences strives to deliver meaningful treatment options and a better patient experience in order to meet the needs of each person we serve. Merz Neurosciences is an important contributor to the U.S. neurosciences space, offering a well-balanced product portfolio that includes the neurotoxin Xeomin<sup>®</sup> (incobotulinumtoxinA), the anticholinergic Cuvposa<sup>™</sup> (glycopyrrolate) Oral Solution and the Prolaryn<sup>™</sup> family of products.

To learn more about Merz Neurosciences and their U.S. product portfolio, please visit [www.merzusa.com/neurosciences](http://www.merzusa.com/neurosciences).

### **XEOMIN<sup>®</sup> IMPORTANT CONSUMER SAFETY INFORMATION**

Read the Medication Guide before you start receiving XEOMIN<sup>®</sup> (Zeo-min) and each time XEOMIN<sup>®</sup> 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](http://www.xeomin.com) to obtain the FDA-approved product labeling
- Call 1-888-4-XEOMIN

**Uses** XEOMIN<sup>®</sup> 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<sup>®</sup>)

It is not known whether XEOMIN<sup>®</sup> is safe or effective in children.

### **Warnings**

**XEOMIN<sup>®</sup> 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<sup>®</sup>:**

- **Problems with swallowing, speaking, or breathing can happen within hours to weeks after an injection of XEOMIN<sup>®</sup>** 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<sup>®</sup>.
- 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<sup>®</sup>.
- 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<sup>®</sup> 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<sup>®</sup> if you:** are allergic to XEOMIN<sup>®</sup> or any of the ingredients in XEOMIN<sup>®</sup> (see the end of this Guide for a list of ingredients in XEOMIN<sup>®</sup>), had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB

(Myobloc<sup>®</sup>), onabotulinumtoxinA (Botox<sup>®</sup>, Botox<sup>®</sup> Cosmetic), or abobotulinumtoxinA (Dysport<sup>®</sup>) or have a skin infection at the planned injection site.

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**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<sup>®</sup> can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XEOMIN<sup>®</sup> passes into breast milk.

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**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<sup>®</sup> 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.**

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**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<sup>®</sup>), onabotulinumtoxinA (BOTOX<sup>®</sup>, BOTOX<sup>®</sup> COSMETIC) and abobotulinumtoxinA (DYSPORT<sup>®</sup>) in the past. Be sure your doctor knows exactly which product you received. The dose of XEOMIN<sup>®</sup> 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.**

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**Possible Side Effects**

**XEOMIN<sup>®</sup> can cause serious side effects that can be life threatening. See “Warnings.”**

**The most common side effects of XEOMIN<sup>®</sup> 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<sup>®</sup> may cause other serious side effects including** allergic reactions.

Symptoms of an allergic reaction to XEOMIN<sup>®</sup> 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<sup>®</sup>. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **Directions**

- XEOMIN<sup>®</sup> is a shot (injection) that your doctor will give you.
- XEOMIN<sup>®</sup> is injected into your affected muscles.
- Your doctor may change your dose of XEOMIN<sup>®</sup> 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](#).

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