

MEDICATION GUIDE
MYOBLOC® (My-o-block)
(rimabotulinumtoxinB)
injection, for intramuscular or intraglandular use

What is the most important information I should know about MYOBLOC?

MYOBLOC 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 MYOBLOC:

- **Problems swallowing, speaking, or breathing.** These problems can happen hours to weeks after an injection of MYOBLOC 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 MYOBLOC.
 - People with certain breathing problems may need to use muscles in their neck to help them breathe. These people may be at greater risk for serious breathing problems with MYOBLOC.
 - 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 MYOBLOC 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 (dysphonia)
 - trouble saying words clearly (dysarthria)
 - loss of bladder control
 - trouble breathing
 - trouble swallowing (dysphagia)

These symptoms can happen hours to weeks after you receive an injection of MYOBLOC.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See **“What should I avoid while receiving MYOBLOC?”**

What is MYOBLOC?

MYOBLOC is a prescription medicine used in adults that is injected into:

- muscles and used to treat the abnormal head position and neck pain that happens with cervical dystonia (CD).
- glands that make saliva and is used to treat long-lasting (chronic) drooling (sialorrhea).

It is not known whether MYOBLOC is safe or effective in children.

Do not receive MYOBLOC if you:

- are allergic to MYOBLOC or any of the ingredients in MYOBLOC. See the end of this Medication Guide for a list of ingredients in MYOBLOC.
- had an allergic reaction to any other botulinum toxin product such as BOTOX®, BOTOX® Cosmetic (onabotulinumtoxinA), DYSPORT® (abobotulinumtoxinA), or XEOMIN® (incobotulinumtoxinA).
- have a skin infection at the planned injection site.

Before receiving MYOBLOC, 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 MYOBLOC?”**
- had any side effect from any botulinum toxin product in the past.
- a breathing problem, 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.

Tell your doctor if you:

- are pregnant or plan to become pregnant. It is not known if MYOBLOC can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if MYOBLOC passes into breast milk.

MYOBLOC® (rimabotulinumtoxinB) injection, for intramuscular or intraglandular use

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. **Talk to your doctor before you take any new medicine after you receive MYOBLOC.**

Using MYOBLOC 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 MYOBLOC in the past. Especially tell your doctor if you:**

- have received any other botulinum toxin product in the last 4 months.
- have received injections of botulinum toxin such as BOTOX®, BOTOX® Cosmetic (onabotulinumtoxinA), DYSPORT® (abobotulinumtoxinA), or XEOMIN® (incobotulinumtoxinA) in the past. Be sure your doctor knows exactly which product you received.
- have recently received an antibiotic by injection.
- take muscle relaxants.
- take an allergy or cold medicine.
- take a sleep 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 should I receive MYOBLOC?

- MYOBLOC is a shot (injection) that your doctor will give you.
- MYOBLOC is injected into your affected muscles or glands.
- Your doctor may give you another dose of MYOBLOC after 12 weeks or longer, if it is needed.
- Your doctor may change your dose of MYOBLOC, until you and your doctor find the best dose for you.

What should I avoid while receiving MYOBLOC?

MYOBLOC may cause loss of strength or general muscle weakness or vision problems within hours to weeks of receiving MYOBLOC. **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 MYOBLOC?”**

What are the possible side effects of MYOBLOC?

MYOBLOC can cause serious side effects including:

See “What is the most important information I should know about MYOBLOC?”

- allergic reactions. Symptoms of an allergic reaction to MYOBLOC may include: itching, rash, redness, swelling, wheezing, trouble breathing, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing, or trouble breathing, or if you get dizzy or faint.

The most common side effects of MYOBLOC in people with cervical dystonia include:

• dry mouth	• injection site discomfort or pain
• trouble swallowing (dysphagia)	• headache

The most common side effects of MYOBLOC in people with sialorrhea include dry mouth and trouble swallowing (dysphagia).

These are not all the possible side effects of MYOBLOC. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to US WorldMeds at 1-888-461-2255.**

General information about the safe and effective use of MYOBLOC.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

You can ask your doctor or pharmacist for information about MYOBLOC that is written for healthcare professionals.

What are the ingredients in MYOBLOC?

Active ingredient: botulinum toxin type B

Inactive ingredients: albumin human, sodium chloride and sodium succinate.

Manufactured by: Solstice Neurosciences, LLC, Louisville, KY 40241

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For more information about MYOBLOC call 1-888-461-2255 or go to www.MYOBLOC.com.