

MEDICATION GUIDE

Myobloc® (My-o-block)

(rimabotulinumtoxinB)

Injection

Read the Medication Guide that comes with MYOBLOC before you start using it and each time MYOBLOC is given to you. There may be new information. This information does not take the place of talking with 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 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 usually because the muscles that you use to breathe and swallow can 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 who need to use muscles in their neck to help them breathe may have more serious breathing problems with MYOBLOC.
- Swallowing problems may last for several months. People who can not 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

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 that is injected into muscles and used to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.

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

It is not known whether MYOBLOC is safe or effective for other types of muscle spasms.

Who should not take MYOBLOC?

Do not take 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[®] or Dysport[™]
- have a skin infection at the planned injection site

What should I tell my doctor before taking 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?"
- allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- a breathing problem, such as asthma or emphysema
- swallowing problems
- bleeding problems
- plans to have surgery

Tell your doctor if you:

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

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products. 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 four months
- have received injections of botulinum toxin, such as Botox[®]/Botox Cosmetic[®] (onabotulinumtoxinA) or Dysport[™] (abobotulinumtoxinA) 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 take MYOBLOC?

- MYOBLOC is an injection that your doctor will give you.
- MYOBLOC is injected into the affected muscles.
- 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 taking MYOBLOC?

MYOBLOC may cause loss of strength or general muscle weakness or vision problems within hours to weeks of taking 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. See "What is the most important information I should know about MYOBLOC?"

Other side effects of MYOBLOC include:

- dry mouth
- indigestion
- injection site discomfort or pain
- headache
- allergic reactions. Symptoms of an allergic reaction to MYOBLOC may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or fainting. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint.

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 MYOBLOC. 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 MYOBLOC:

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

This Medication Guide summarizes the most important information about MYOBLOC. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about MYOBLOC that is written for healthcare professionals. For more information about MYOBLOC call 1-888-461-2255 or go to www.MYOBLOC.com.

What are the ingredients in MYOBLOC?

Active ingredient: botulinum toxin type B

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

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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