MYOBLOC® (rimabotulinumtoxinB) Injection is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Please see the full Important Safety Information on pages 12-13, the Boxed WARNING and the accompanying full Prescribing Information and Medication Guide.
Cervical Dystonia: It’s a Pain in the Neck!

Cervical dystonia (CD) affects thousands of people every year. CD is a neurological movement disorder that causes the muscles in your neck to contract (tighten) involuntarily. This muscle tightening can cause you to hold your head and neck in painful, abnormal positions. These positions can cause you to face challenges and discomfort in your day-to-day life.¹
What Causes CD?

Normally, your brain sends chemical signals to your head and neck muscles to keep their movements smooth and controlled. In patients with CD, these signals work improperly. When acetylcholine, one of the chemical signals, is released at above-normal amounts, it causes muscles to be tense and overactive.

In some cases of CD, causes can be linked to neck, head and shoulder injuries, and certain drugs. While the exact cause is not clear, research is still being conducted to explore the factors that can contribute to CD.

This patient guide will help you understand CD. You will learn what to expect from your MYOBLOC treatment, should your healthcare provider recommend it.

IMPORTANT SAFETY INFORMATION

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of MYOBLOC and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses [see Warnings and Precautions].
What Are the Symptoms of CD?

Typically, CD symptoms are gradual and include:

- Abnormal and painful turning of head and neck\(^2\)
- Increasing neck muscle tightness or spasms\(^2\)
- Neck pain\(^3\)
- Uncomfortable pulling in the neck\(^2\)
- Tremors of the head and neck\(^6\)
- Limited range of motion\(^4\)

**IMPORTANT SAFETY INFORMATION**

MYOBLOC is contraindicated in patients with a known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

Treatment with MYOBLOC and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant effects occur, additional respiratory muscles may be involved.
Pain Is a Common Complaint of Most Patients with CD

- 75% of patients with CD reported neck pain as a common symptom\(^5\)
- Of those patients, nearly 7 out of 10 said the pain was moderate or severe\(^6\)
- CD pain may interfere with your work and social life\(^1,5,7,8\)

The Four Most Common Postures Associated with CD

- TORTICOLLIS
- RETROCOLLIS
- ANTEROCOLLIS
- LATEROCOLLIS
Treating CD

Establishing an effective treatment regimen requires a partnership between you and your healthcare provider. Your response to treatment may differ from other patients’ responses, therefore, it is very important to keep an open dialogue with your healthcare provider.

There are three main CD treatment approaches:

- Botulinum toxin therapy
- Oral medications
- Surgery

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What is MYOBLOC?

MYOBLOC is a unique botulinum toxin therapy, approved by the FDA as an effective treatment for CD in adults. MYOBLOC is the only botulinum toxin type B available. In multiple clinical studies, MYOBLOC injections have demonstrated an improvement in abnormal head positioning and neck pain associated with CD.9,10,11

How does MYOBLOC work?

MYOBLOC disables a protein that would typically trigger the release of excessive acetylcholine, which causes muscles to become tense and spasm. When your healthcare provider injects MYOBLOC into affected muscles, it blocks the release of acetylcholine, allowing them to relax.12 Over time, your healthcare provider will adjust the dose of MYOBLOC to achieve maximum pain relief and muscle-spasm control.

IMPORTANT SAFETY INFORMATION

The potency Units of MYOBLOC are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of MYOBLOC cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

MYOBLOC is contraindicated for use in patients with infection at the proposed injection site(s).
TREATMENT

What to Expect from Your MYOBLOC Treatment

• Treatment is administered in your healthcare provider’s office
• Small amounts of MYOBLOC will be injected into your affected muscles
• You may need adjustments to your dosing to receive maximum benefit

Patients who respond to MYOBLOC may:

• Notice improvements to their head and neck position\textsuperscript{13}
• Experience pain relief as early as two weeks after injection\textsuperscript{14,15}
• Feel relief for 12-16 weeks\textsuperscript{9,10}
• Maintain their daily activities between doses

IMPORTANT SAFETY INFORMATION

Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several months, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised.
Most Common Side Effects with MYOBLOC

Side effects with MYOBLOC are generally mild to moderate and temporary, and are more common with higher doses. The most frequently reported side effects with MYOBLOC were dry mouth, swallowing difficulties, indigestion and injection site pain. Dry mouth and swallowing difficulties were the side effects that most often resulted in discontinuation of treatment.13
Patient Assistance Services

If you need financial assistance in obtaining your MYOBLOC treatment, there are programs available for eligible patients.

• Insured, but need help affording MYOBLOC treatment?
  – The Co-Pay Assistance Program helps eligible patients with CD afford out-of-pocket and related administration expenses associated with MYOBLOC injection.
  – With no limit per injection, eligible patients may receive up to $4,000 per year of assistance with permitted out-of-pocket expenses.
  – For the full eligibility requirements and program details, visit www.myobloc-reimbursement.com.

• Uninsured, but cannot afford to pay for MYOBLOC treatment?
  – The Patient Assistance Program for MYOBLOC may be able to provide MYOBLOC at no cost to you.
  – For full program details, visit www.myobloc-reimbursement.com.

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IMPORTANT SAFETY INFORMATION

Treatment of cervical dystonia with botulinum toxins may weaken neck muscles that serve as accessory muscles of ventilation. This may result in a critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these accessory muscles. There have been postmarketing reports of serious breathing difficulties, including respiratory failure, in cervical dystonia patients. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

For more information about our Patient Programs, please call the Circle of Care at 1-888-461-2255, Option 3, 8:00 AM to 8:00 PM ET, Monday through Friday.
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Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of MYOBLOC.
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Only 9 subjects without a prior history of tolerating injections of type A botulinum toxin have been studied. Treatment of botulinum toxin naive patients should be initiated at lower doses of MYOBLOC.

Co-administration of MYOBLOC and aminoglycosides or other agents interfering with neuromuscular transmission [e.g., curare-like compounds] should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes at the same time or within less than 4 months of each other is unknown. However, neuromuscular paralysis may be potentiated by co-administration or overlapping administration of different botulinum toxin serotypes.

REFERENCES


It is not known whether MYOBLOC can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. MYOBLOC should be given to a pregnant woman only if clearly needed.

The most commonly reported adverse events associated with MYOBLOC treatment in all studies were dry mouth, dysphagia, dyspepsia, and injection site pain. Dry mouth and dysphagia were the adverse reactions most frequently resulting in discontinuation of treatment. There was an increased incidence of dysphagia with increased dose in the sternocleidomastoid muscle. The incidence of dry mouth showed some dose-related increase with doses injected into the splenius capitis, trapezius and sternocleidomastoid muscles.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-888-461-2255, Option 2. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
For more information about MYOBLOC and our Patient Assistance Services, please call the Circle of Care at 1-888-461-2255, Option 3, 8:00 AM to 8:00 PM ET, Monday through Friday.