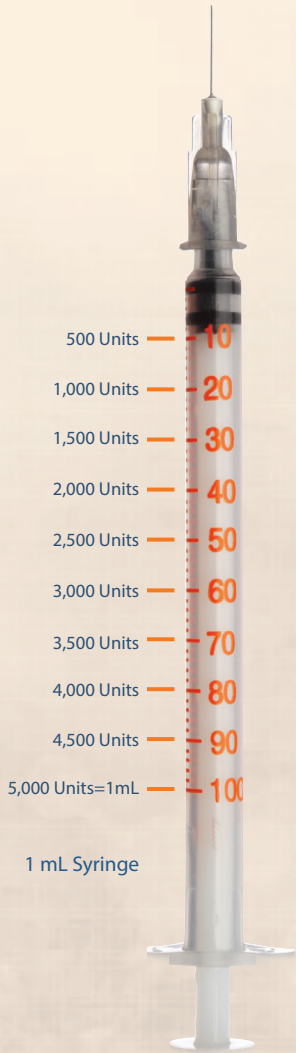
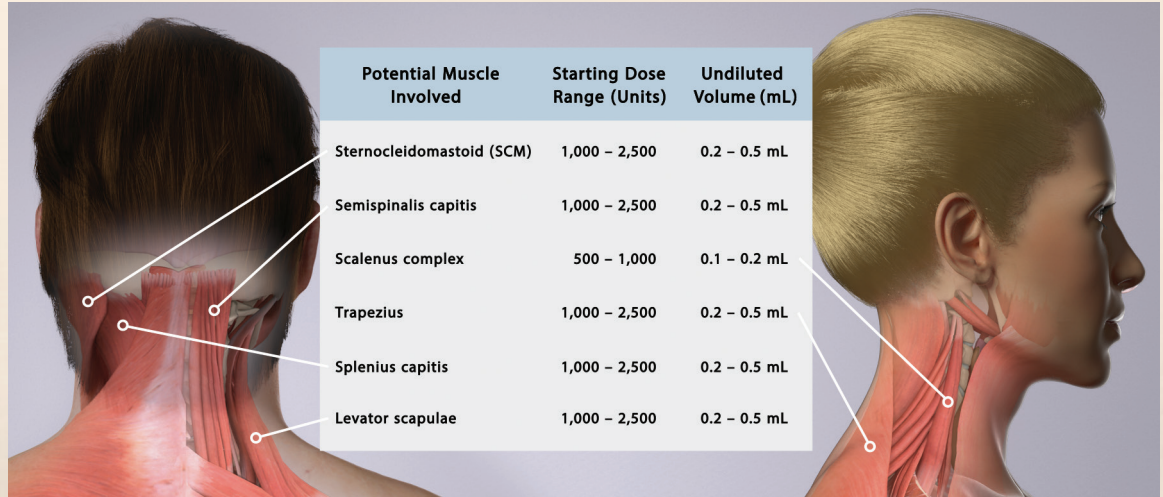


DOSING GUIDE

Please see Important Safety Information on the reverse side, the Boxed WARNING, and accompanying full Prescribing Information and Medication Guide



MYOBLOC is Convenient and Easy to Dose

Potential Muscle Involved	Starting Dose Range (Units)	Undiluted Volume (mL)
Sternocleidomastoid (SCM)	1,000 – 2,500	0.2 – 0.5 mL
Semispinalis capitis	1,000 – 2,500	0.2 – 0.5 mL
Scalenus complex	500 – 1,000	0.1 – 0.2 mL
Trapezius	1,000 – 2,500	0.2 – 0.5 mL
Splenius capitis	1,000 – 2,500	0.2 – 0.5 mL
Levator scapulae	1,000 – 2,500	0.2 – 0.5 mL

- The recommended initial total dose of MYOBLOC for patients with a prior history of tolerating botulinum toxin injections is 2,500 to 5,000 Units, divided among affected muscles¹
- The dosing recommendations in the chart above are based on controlled clinical trials in which 5,000 Units of MYOBLOC were divided among 2–4 affected muscles²
- Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dose
 - Subsequent dosing should be optimized according to the patient's individual response

Dosing Considerations:

- Patient weight and muscle bulk³
- CD symptom severity
- Risk of dysphagia¹
- Reduction of dosage is called for in patients:
 - With smaller neck muscles
 - Who require bilateral injections into the SCM

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.

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].

MYOBLOC is Ready to Use and Requires No Mixing

- Solution contains 5,000 Units of botulinum toxin type B per mL 500 Units
0.1mL
- 3 single-use vial sizes
 - 2,500 Units in 0.5 mL
 - 5,000 Units in 1 mL
 - 10,000 Units in 2 mL



To order MYOBLOC, call 1-888-461-2255, Option 1. For information on Reimbursement for MYOBLOC, including Billing and Coding, visit www.myobloc-reimbursement.com

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.

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

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.

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.

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.

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.

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 naïve 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.

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.

Please see the full Prescribing Information, including Boxed WARNING and Medication Guide.

References 1. MYOBLOC® US Prescribing Information. Solstice Neurosciences, LLC; Louisville, KY;2010. 2. Data on file; MYO-032-0108. Solstice Neurosciences, LLC; Louisville, KY;2007. 3. Jankovic J. Dystonias, choreas, athetosis, and ballism. In: Goldman L, Ausiello D, eds. *CECIL TEXTBOOK OF MEDICINE*. Philadelphia, PA: Saunders; 2004:2312-2314.

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NEUROSCIENCES
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MYOBLOC[®]
rimabotulinumtoxinB
Injection [5,000 Units/mL]
www.myobloc.com

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