MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]

Actor portrayals.

INJECTION TRAINING RESOURCE GUIDE

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNING: DISTANT SPREAD OF TOXIN EFFECT

See full prescribing information for complete boxed WARNING.

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 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, particularly in those patients who have an underlying condition that would predispose them to these symptoms.

Please see full Prescribing Information and additional Important Safety Information throughout.

WHAT CAN I LEARN FROM THIS GUIDE?

This Injection Training Resource Guide provides important information on cervical dystonia (CD) and how MYOBLOC® is a first-line treatment option[1] that was proven to be an effective treatment for CD.[2] You will learn about the different muscles involved in CD and techniques for approaching a patient's treatment.

Table of Contents

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

MYOBLOC is contraindicated in patients with:

- A known hypersensitivity to any botulinum toxin product or to any of the components in the formulation
- Infection at the proposed injection site(s)

SYRINGE-READY WITH FLEXIBLE DOSING

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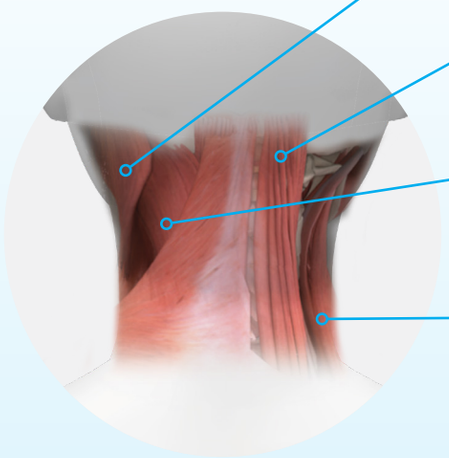
Injection [5,000 Units/mL]

DOSING IS BASED ON CLINICAL TRIALS
TOTAL DOSE DIVIDED AMONG 2 TO 4 AFFECTED MUSCLES[2,3]



STERNOCLEIDOMASTOID
Starting dose: 1,000 - 2,500 Units
Undiluted volume: 0.2 - 0.5 mL

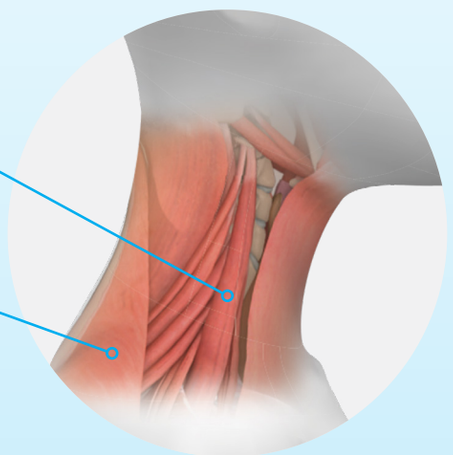
SEMISPINALIS CAPITIS
Starting dose: 1,000 - 2,500 Units
Undiluted volume: 0.2 - 0.5 mL

SPLENIUS CAPITIS
Starting dose: 1,000 - 2,500 Units
Undiluted volume: 0.2 - 0.5 mL

LEVATOR SCAPULAE
Starting dose: 1,000 - 2,500 Units
Undiluted volume: 0.2 - 0.5 mL

SCALENE COMPLEX
Starting dose: 500 - 1,000 Units
Undiluted volume: 0.1 - 0.2 mL

TRAPEZIUS
Starting dose: 1,000 - 2,500 Units
Undiluted volume: 0.2 - 0.5 mL



SYRINGE-READY WITH FLEXIBLE DOSING - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

INSTRUCTIONS FOR SAFE USE

- **Lack of Interchangeability Between Botulinum Toxin Products**
  The potency units of MYOBLOC are specific to the preparation and biological activity assay method utilized. Due to differences in the aspects of this assay such as the vehicle, dilution scheme, and laboratory protocols for various potency assays, potency units 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.

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SYRINGE-READY WITH FLEXIBLE DOSING

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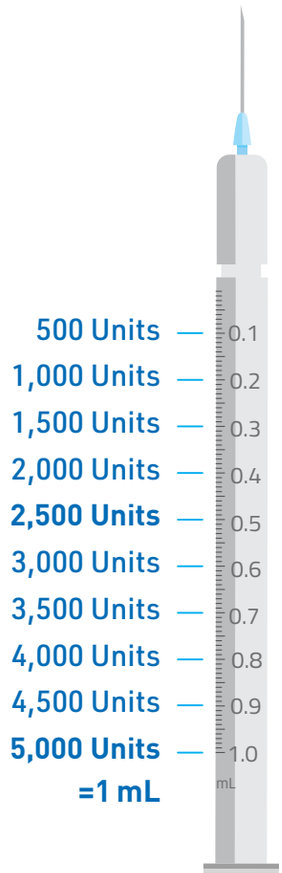
Injection [5,000 Units/mL]



DOSING RECOMMENDATIONS:

- 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 muscles[2]
- The dosing recommendations on page 2 are based on controlled clinical trials in which 5,000 Units of MYOBLOC were divided among 2 to 4 affected muscles[3]
- Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dose[2]
- Subsequent dosing should be determined by the patient's individual response[2]

DOSING CONSIDERATIONS:

- Patient weight and muscle bulk
- Cervical dystonia symptom severity
- Risk of swallowing or breathing difficulties in patients with neuromuscular disorders[2]
- Reduction of dosage is called for in patients with smaller neck muscles and who require bilateral injections into the sternocleidomastoid
- The duration of effect has been observed in studies to be between 12 and 16 weeks at doses of 5,000 Units or 10,000 Units[2]

Please see full Prescribing Information, including Boxed WARNING, and Important Safety Information throughout.

COMMON POSTURES[4,5]

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]

FOUR MOST COMMON POSTURES IN CD

Patients may present with a combination of postures, as well as sustained or jerky movements.

ANTEROCOLLIS (flexion)

Forward head posturing

Primary Muscles

Scalene complex

Secondary Muscles

Bilateral sternocleidomastoid (SCM)

LATEROCOLLIS (lateral tilt)

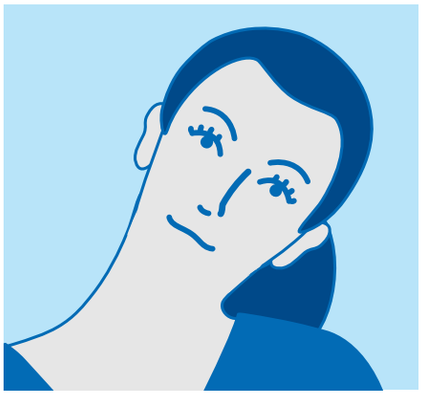
Turning, flexing, or extending of the neck to the side

Primary Muscles

Splenius capitis
Levator scapulae
Longissimus
SCM

Secondary Muscles

Ipsilateral scalene complex
Splenius cervicis



COMMON POSTURES IN CD - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Hypersensitivity Reactions**
  Serious hypersensitivity reactions have been reported with botulinum toxin products. Angioedema, urticaria, and rash have occurred with MYOBLOC treatment. Hypersensitivity reactions can also include anaphylaxis, serum sickness, soft tissue edema, and dyspnea. If serious and/or immediate hypersensitivity reactions occur, discontinue further injection of MYOBLOC and institute appropriate medical therapy immediately. The use of MYOBLOC in patients with a known hypersensitivity to any botulinum neurotoxin or to any of the excipients (human albumin, sucrose), could lead to a life-threatening allergic reaction.

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COMMON POSTURES[4,5]

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]

TORTICOLLIS (rotation)

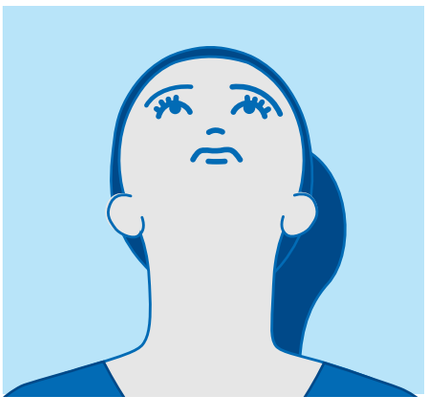
Sideways or lateral rotation of the head and twisting of the neck

Primary Muscles

Ipsilateral splenius capitis
Contralateral SCM
Splenius cervicis
Levator scapulae

Secondary Muscles

Inferior oblique longus capitis
Ipsilateral longissimus
Ipsilateral semispinalis
Longus capitis
Trapezius



RETROCOLLIS (extension)

Backward head posturing

Primary Muscles

Bilateral splenius capitis
Levator scapulae
Longissimus
Semispinalis capitis

Secondary Muscles

Bilateral trapezius
Splenius cervicis

MUSCLES INVOLVED IN CD

MYOBLOC®
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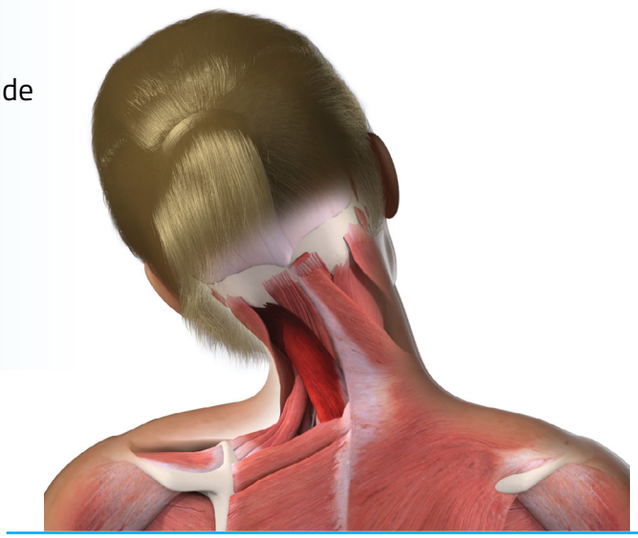
SPLENIUS CERVICIS

Primary function(s):

Laterally bends and rotates head to side of active muscles; bilateral activation extends head and neck

Postures:

Laterocollis, retrocollis, torticollis



The full Prescribing Information does not offer dosing guidelines on the splenius cervicis.*

Origin	Localization	Insertion
Inferior half of ligamentum nuchae and spinous processes of C7 to T4 vertebrae	At its inferior portion, the splenius cervicis muscle meshes with the splenius capitis/torticollis	Posterior tubercles of transverse processes of C1 to C4 vertebrae

***Recommended initial dose for patients with a prior history of tolerating botulinum toxin injections is 2,500 to 5,000 Units divided among affected muscles. Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dose. In clinical trials, there was an increased incidence of dysphagia with increased dose in the sternocleidomastoid muscle.**

MUSCLES INVOLVED IN CD - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Dysphagia and Breathing Difficulties**

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.

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MUSCLES INVOLVED IN CD

MYOBLOC®
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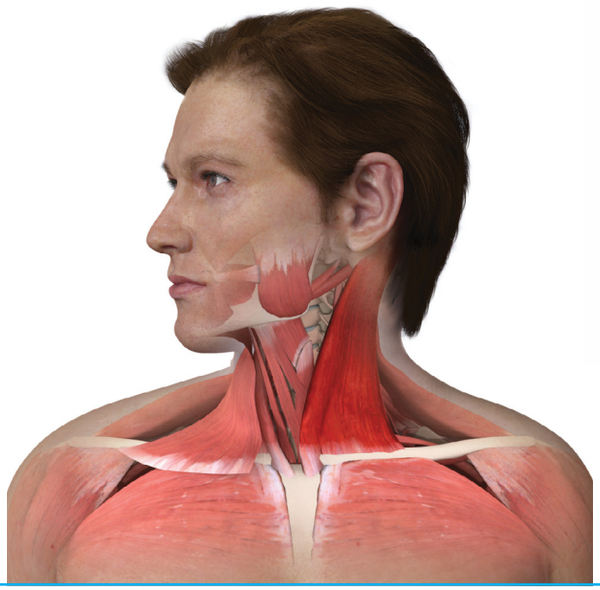
Injection [5,000 Units/mL]

STERNOCLEIDOMASTOID



Primary function(s):

Tilts head laterally; rotates neck so head is turned superiorly toward opposite side; bilateral contraction flexes neck

Postures:

Anterocollis, laterocollis, torticollis

Starting Dose Range: 1,000 – 2,500 Units*
Undiluted Volume: 0.2 – 0.5 mL

Origin	Localization	Insertion
▪ Sternal head – upper part of anterior surface of manubrium ▪ Clavicular head – superior surface of medial third of clavicle	Readily localized with contralateral rotation (may be hypertrophied in contralateral torticollis); providing resistance may accentuate it further	Lateral surface of mastoid process and lateral half of superior nuchal line

In clinical trials, there was an increased incidence of dysphagia with increased dose in the sternocleidomastoid muscle.

In clinical trials, there was an increased incidence of dysphagia with increased dose in the SCM muscle.

MUSCLES INVOLVED IN CD - *(continued)*

MUSCLES INVOLVED IN CD

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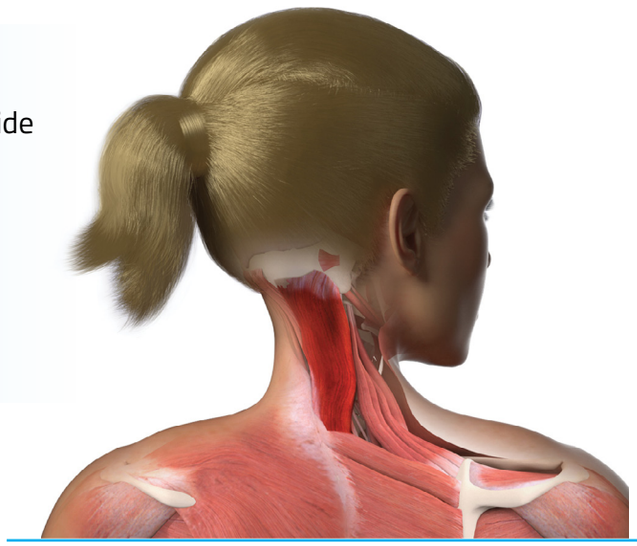
SPLENIUS CAPITIS

Primary function(s):

Laterally bends and rotates head to side of active muscles; bilateral activation extends head and neck

Postures:

Laterocollis, retrocollis, torticollis



Starting Dose Range: 1,000 – 2,500 Units*
Undiluted Volume: 0.2 – 0.5 mL

Origin	Localization	Insertion
Inferior half of ligamentum nuchae and spinous processes of C7 to T4 vertebrae	Just superior to the levator in the posterior triangle	Fibers run superolaterally to mastoid process of temporal bone and lateral third of superior nuchal line of occipital bone

***Recommended initial dose for patients with a prior history of tolerating botulinum toxin injections is 2,500 to 5,000 Units divided among affected muscles. Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dose.**

MUSCLES INVOLVED IN CD - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Dysphagia and Breathing Difficulties (cont'd)

– **Cervical Dystonia:** 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.

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MUSCLES INVOLVED IN CD

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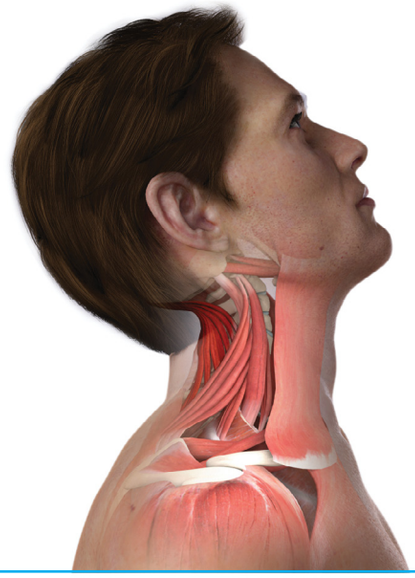
Injection [5,000 Units/mL]

SEMISPINALIS CAPITIS



Primary function(s):

Extends neck and rotates head toward opposite side

Postures:

Laterocollis, retrocollis, torticollis

Starting Dose Range: 1,000 – 2,500 Units*
Undiluted Volume: 0.2 – 0.5 mL

Origin	Localization	Insertion
Transverse processes of C4 to T6 vertebrae	Two fingerbreadths lateral to the midline	Between superior and inferior nuchal line of the occipital bone

MUSCLES INVOLVED IN CD - *(continued)*

MUSCLES INVOLVED IN CD

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Injection [5,000 Units/mL]

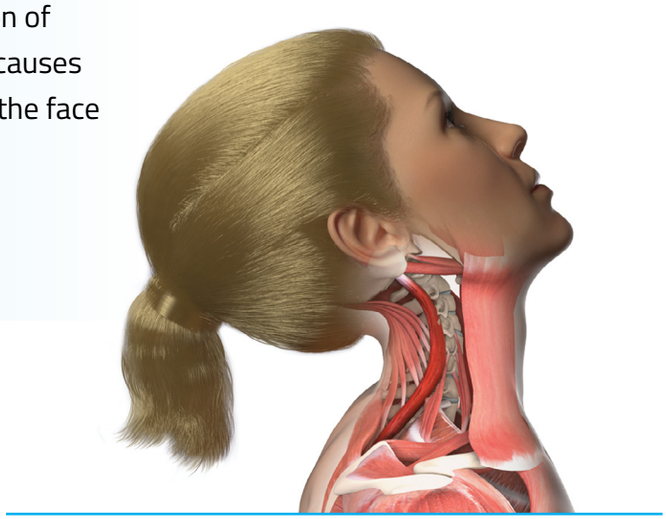
LONGISSIMUS

Primary function(s):

Bilateral activity will produce extension of the neck and head; unilateral activity causes ipsilateral rotation and tilt and brings the face toward the shoulder

Postures:

Laterocollis, retrocollis, torticollis



The full Prescribing Information does not offer dosing guidelines on the longissimus.*

Origin	Localization	Insertion
Transverse processes (T1-T4) and articular processes (C5-C7) of inferior vertebral levels	Two fingerbreadths below the lower palpable border of the skull, and 3 fingerbreadths lateral to midline	Transverse processes at superior vertebral levels (C2-C6) or the mastoid process

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MUSCLES INVOLVED IN CD - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Dysphagia and Breathing Difficulties (cont'd)

– **Pre-Existing Neuromuscular Disorders:** 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.

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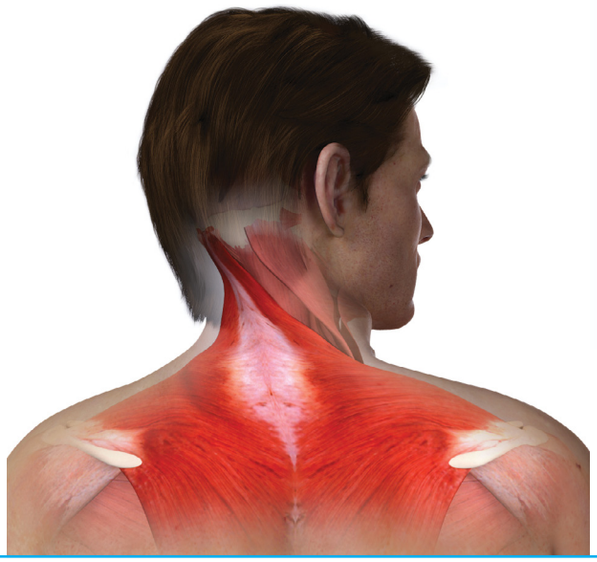
TRAPEZIUS



Primary function(s):

Elevates, retracts, and rotates scapula; rotates head toward opposite side

Postures:

Laterocollis, retrocollis, torticollis

Starting Dose Range: 1,000 – 2,500 Units*
Undiluted Volume: 0.2 – 0.5 mL

Origin	Localization	Insertion
Medial third of superior nuchal line; external occipital protuberance, nuchal ligament, and spinous processes of C7 to T12 vertebrae	Anterior border makes up the posterior leg of the posterior triangle	Lateral third of the clavicle, acromion, and spine of scapula

MUSCLES INVOLVED IN CD - *(continued)*

MUSCLES INVOLVED IN CD

MYOBLOC®
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Injection [5,000 Units/mL]

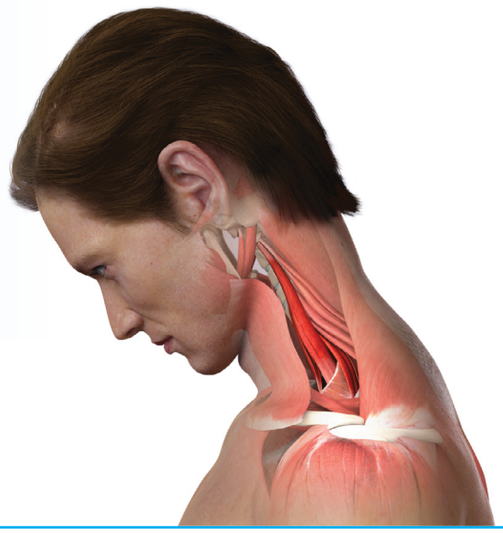
SCALENE COMPLEX

Primary function(s):

Anterior – elevates first rib; flexes and rotates neck laterally
Middle and Posterior – flexes neck laterally

Postures:

Anterocollis, laterocollis



Starting Dose Range: 500 – 1,000 Units*
Undiluted Volume: 0.1 – 0.2 mL

Origin	Localization	Insertion
Anterior – transverse processes of C4 to C6 vertebrae Middle and Posterior – tubercles of transverse processes of C4 to C6 vertebrae	Anterior – deep to the SCM Middle – two fingerbreadths anterior to the edge of the trapezius (largest of the scalenes) Posterior – deepest of the scalenes	Anterior – first rib Middle – superior surface of the first rib, posterior groove for subclavian artery Posterior – external border of second rib

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MUSCLES INVOLVED IN CD - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Human Albumin and Transmission of Viral Diseases**

  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 and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

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MUSCLES INVOLVED IN CD

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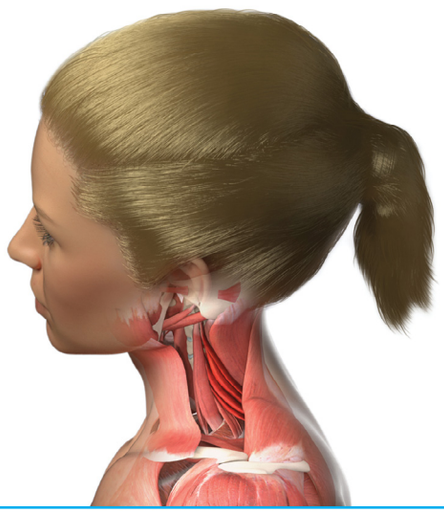
LEVATOR SCAPULAE

Primary function(s):

Elevates scapula

Postures:

Laterocollis, retrocollis, torticollis



Starting Dose Range: 1,000 – 2,500 Units*
Undiluted Volume: 0.2 – 0.5 mL

Origin	Localization	Insertion
Posterior tubercles of transverse processes of C1 to C4 vertebrae	May be palpated immediately anterior to the anterior edge of the trapezius, at the angle of the neck	Superior part of the medial border of scapula

IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

MYOBLOC is contraindicated in patients with:

- A known hypersensitivity to any botulinum toxin product or to any of the components in the formulation
- Infection at the proposed injection site(s)

WARNINGS AND PRECAUTIONS

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- **Hypersensitivity Reactions**
  Serious hypersensitivity reactions have been reported with botulinum toxin products. Angioedema, urticaria, and rash have occurred with MYOBLOC treatment. Hypersensitivity reactions can also include anaphylaxis, serum sickness, soft tissue edema, and dyspnea. If serious and/or immediate hypersensitivity reactions occur, discontinue further injection of MYOBLOC and institute appropriate medical therapy immediately. The use of MYOBLOC in patients with a known hypersensitivity to any botulinum neurotoxin or to any of the excipients (human albumin, sucrose), could lead to a life-threatening allergic reaction.
- **Dysphagia and Breathing Difficulties**
  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.
  - **Cervical Dystonia:** 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.
  - **Pre-Existing Neuromuscular Disorders:** 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.

IMPORTANT SAFETY INFORMATION - *(continued)*

IMPORTANT SAFETY INFORMATION (cont'd)

MYOBLOC®
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WARNINGS AND PRECAUTIONS (cont'd)

- **Human Albumin and Transmission of Viral Diseases**
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MOST COMMON ADVERSE REACTIONS (>5% of patients and >5% more than placebo)

Cervical Dystonia: dry mouth, dysphagia, injection site pain, headache

DRUG INTERACTIONS

Aminoglycosides and Other Agents Interfering with Neuromuscular Transmission: 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. **Anticholinergic Drugs:** Use of anticholinergic drugs after administration of MYOBLOC may potentiate systemic anticholinergic effects. **Other Botulinum Neurotoxin Products:** The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. **Muscle Relaxants:** Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of MYOBLOC.

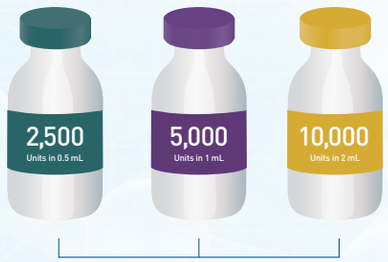
Please see full Prescribing Information, including Boxed WARNING, and additional Important Safety Information throughout.

REFERENCES: 1. American Academy of Neurology. *Practice Guideline Update Summary: Botulinum Neurotoxin for the Treatment of Blepharospasm , Cervical Dystonia, Adult Spasticity, and Headache.* American Academy of Neurology; 2016. **2.** MYOBLOC. US Prescribing Information. Solstice Neurosciences, LLC. **3.** Data on file. Solstice Neurosciences, LLC. **4.** Dystonia Medical Research Foundation. Homepage. Accessed November 2021. https://dystonia-foundation.org/what-is-dystonia/types-dystonia/cervical-dystonia/. **5.** Chan J, Brin MF, Fahn S. Idiopathic cervical dystonia: clinical characteristics. *Mov Disord.* 1991;6(2):119-126. doi:10.1002/mds.870060206

MYOBLOC IS THE ONLY FDA-APPROVED TYPE B TOXIN[2]

SYRINGE-READY[2] FIRST-LINE TREATMENT FOR CD[1]

MYOBLOC is ready to use and requires no mixing



3 single-dose vial sizes*

*For single-patient use.

Learn about our injection training program

To order MYOBLOC, call 1-888-461-2255, Option 1.

For information on Reimbursement for MYOBLOC, including Billing and Coding, visit www.myoblochcp.com

Request MYOBLOC samples today

IMPORTANT SAFETY INFORMATION

WARNING: DISTANT SPREAD OF TOXIN EFFECT

See full prescribing information for complete boxed WARNING.

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 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, particularly in those patients who have an underlying condition that would predispose them to these symptoms.

Please see full Prescribing Information and additional Important Safety Information throughout.

Supernus® Pharmaceuticals

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]