

# ANATOMICAL TREATMENT GUIDE FOR CERVICAL DYSTONIA

Patient Name:	
Date of Birth:	Treatment Date:
Diagnosis:	

#### 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<sup>1</sup>
- 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
- The dosing recommendations in the chart below are based on controlled clinical trials in which 5,000 Units of MYOBLOC were divided among
   2-4 affected muscles<sup>2</sup>; duration of effect in patients responding to treatment in studies was between 12 and 16 weeks at doses of 5,000 or 10,000 Units<sup>1</sup>

STERNOCLEIDOMASTOID	SEMISPINALIS CAPITIS	Muscle	Starting Dose Range (Units)	Undiluted Volume	
	mali III	LEVATOR SCAPULAE	1,000 - 2,500	0.2 - 0.5 mL	SCALENUS COMPLEX
		SCALENUS COMPLEX	500 - 1,000	0.1 - 0.2 mL	
SPLENIUS CAPITIS		SEMISPINALIS CAPITIS	1,000 - 2,500	0.2 - 0.5 mL	TRAPEZIUS
		SPLENIUS CAPITIS	1,000 - 2,500	0.2 - 0.5 mL	TRAFEZIUS
	1110	STERNOCLEIDOMASTOID	1,000 - 2,500	0.2 - 0.5 mL	
	LEVATOR SCAPULAE	TRAPEZIUS	1,000 - 2,500	0.2 - 0.5 mL	11 3 M
	Sternocleidomastoid	Levator scapu	ılae	Other muscle	e(s):
	Right:	Right:		Right:	
F00.11.11	Left:	Left:		Left:	
	Semispinalis capitis	Splenius capit	tis		
1,500 Units — 0.3 2,000 Units — 0.4	Right:	Right:		EMG	Utilized? 🗌 Yes 🗌 No
<b>2,500 Units</b> — 0.4	Left:	Left:		Tota	l units injected:
3,500 Units         0.7         Right: _           4,000 Units         0.8         Left: _           4,500 Units         0.9         Left: _	Scalenus complex	Trapezius			
	Right:	Right:		Unavoidable waste:	
	Left:	-			
5,000 Units — ≣ <sub>1.0</sub> =1 mL	<b>DOSING CONSIDER</b> <ul> <li>Cervical dystonia syr</li> </ul>		<ul> <li>Risk of swallowi</li> </ul>	ng or breathing	difficulties
1-mL Syringe	<ul> <li>Patient weight and r</li> </ul>		in patients with		

#### **INDICATION**

MYOBLOC<sup>®</sup> 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<sup>®</sup> 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 on next page.



\*For single-patient use.

### 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)

#### WARNINGS AND PRECAUTIONS

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.

#### 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

### To order MYOBLOC, call <u>1-888-461-2255</u>, Option 1.

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

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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.
- 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.

# 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. Muscle Relaxants: Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administration of a muscle relaxant before or after administration of MYOBLOC.

Please see full Prescribing Information, including Boxed WARNING.

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

#### **References:**

1. MYOBLOC® US Prescribing Information. Solstice Neurosciences, LLC. 2. Data on file. Solstice Neurosciences, LLC.

MYOBLOC is a registered trademark of Solstice Neurosciences, LLC, a wholly-owned subsidiary of Supernus Pharmaceuticals, Inc. © 2022. Supernus Pharmaceuticals, Inc. MYO.2022-0067 12/22.

