

# DOSING AND INJECTION TRAINING GUIDE FOR CHRONIC SIALORRHEA

#### INDICATION

MYOBLOC® injection is indicated for the treatment of chronic sialorrhea in adults.

#### **IMPORTANT SAFETY INFORMATION**

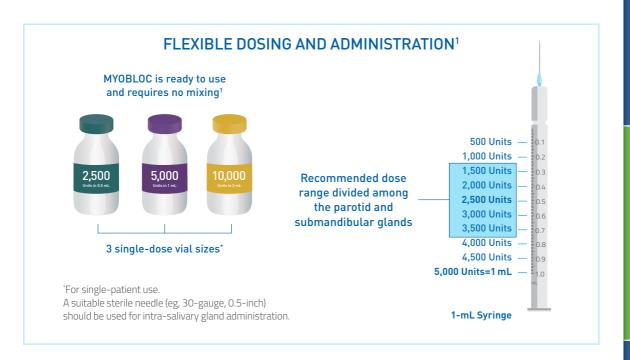
#### **WARNING: DISTANT SPREAD OF TOXIN EFFECT**

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.



#### No mixing makes MYOBLOC® syringe-ready.1



#### CHRONIC SIALORRHEA DOSING GUIDELINES<sup>1</sup>

#### DOSING RECOMMENDATIONS:

- Subsequent dosing and frequency of dosing should be optimized according to the patient's individual response
  - Generally, no more frequent than every 12 weeks
  - Individual patient responses may vary

#### DOSING CONSIDERATIONS:

- Sialorrhea symptom severity
- Risk of swallowing or breathing difficulties in patients with neuromuscular disorders

#### 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.

Please refer to the full <u>Prescribing Information</u>, including Boxed WARNING, and additional Important Safety Information throughout.

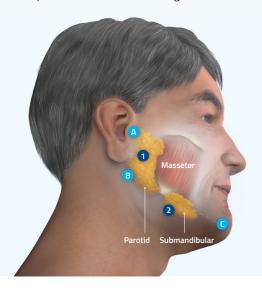
#### MYOBLOC can be injected with or without ultrasound guidance.1



#### GUIDELINES FOR ANATOMICAL LANDMARKS<sup>1</sup>

#### Recommended dosage:

1,500 to 3,500 Units divided among the parotid and submandibular glands



#### Parotid gland injection

- Bisect the distance between the tip of the tragus (Site A) and the angle of the mandible (Site B)
- Inject 1 finger breadth anterior to this site (Injection Site 1)

Starting Dose Range (Units)	Undiluted Volume (mL)
500-1,500 per gland	0.1-0.3 per gland

#### Submandibular gland injection

- Bisect the distance between the angle of the mandible (Site B) and the tip of the chin (Site C)
- Inject 1 finger breadth medial to the inferior surface of the point of bisection (Injection Site 2)

Dose (Units)	Undiluted Volume (mL)
250 per gland	0.05 per gland

#### THE MOST COMMON ADVERSE REACTION WAS DRY MOUTH<sup>1</sup>

Adverse reactions in at least 5% of MYOBLOC-treated patients and greater than placebo in pooled chronic sialorrhea studies

Adverse Reaction	MYOBLOC (%)			PLACEBO (%)
	1,500 U (N=14)*	2,500 U (N=75) <sup>†2</sup>	3,500 U (N=77) <sup>†</sup>	(N=75)
Dry mouth	14	36	39	7
Dental caries	0	7	5	3
Dysphagia	0	9	4	3

<sup>\*</sup>Adverse reactions for 1,500 Unit dose were only evaluated in Study 2.

 $<sup>^{\</sup>dagger}\!$ Adverse reactions for 2,500 Unit and 3,500 Unit doses were evaluated in Studies 1 and 2.



- The majority of dry mouth adverse reactions were mild to moderate<sup>1,2</sup>
- The frequency of common adverse reactions did not appear to be dose-dependent, except in the case of dry mouth¹

Please refer to the full <u>Prescribing Information</u>, including Boxed WARNING, and additional Important Safety Information throughout.

## 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 (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.

#### 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.

 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)

Chronic Sialorrhea: dry mouth, dysphagia

#### **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 refer to the full <u>Prescribing Information</u>, including Boxed WARNING, and additional Important Safety Information throughout.

#### References

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



