CERVICAL DYSTONIA PATIENT PROFILE

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

MEET LYDIA*

AGE: 44

HISTORY:

- Experiencing twisting of her neck with pain in the right suboccipital region, which has gradually worsened over the past 4 years
- Symptoms led her to change jobs
- Has gotten limited relief from physical intervention and oral medication

EXAMINATION:

- Marked torticollis with tilting of her head to the left
- Tremor is present and increased when holding her head in a normal position
- No abnormalities detected in lab analysis and imaging tests

DIAGNOSIS:
Cervical dystonia (spasmodic torticollis)

Do you have adult patients like Lydia in your practice?

All photos within this piece are actor portrayals.

*This is not a real patient. This representation was not designed to reflect efficacy for an individual patient subgroup. Individual results may vary.

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 refer to the full Prescribing Information and additional Important Safety Information on next page.

Early and significant pain reduction

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AS THE FIRST FDA-APPROVED NEUROTOXIN FOR CD, MYOBLOC IS A WELL-STUDIED TREATMENT WITH DEMONSTRATED EFFICACY IN ADULTS[1]

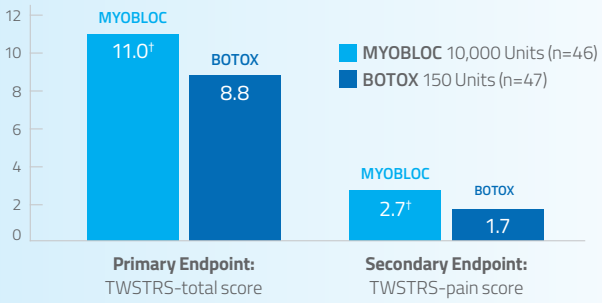
	Toxin A-Responsive[1,2]	Toxin A-Resistant[1,3]	Toxin A-Responsive and Toxin A-Resistant[1,4]
Study	**Study 1**: Randomized, double-blind, multicenter, placebo-controlled, 16-week trial (N=109)	**Study 2**: Randomized, double-blind, multicenter, placebo-controlled, 16-week trial (N=77)	**Study 4**: Randomized, double-blind, multicenter, placebo-controlled, 16-week trial (N=122)
Dose Arms	MYOBLOC 5,000 U (n=36) or 10,000 U (n=37) vs. placebo (n=36)	MYOBLOC 10,000 U (n=39) vs. placebo (n=36)	MYOBLOC 2,500 U (n=31), 5,000 U (n=31) or 10,000 U (n=30) vs. placebo (n=30)
TWSTRS-total score	Significant improvement with MYOBLOC **at Week 4** in all doses tested (primary endpoint)[1-4]		
TWSTRS-pain score	Significant improvement with MYOBLOC **at 4 Weeks** in doses tested (tertiary endpoint)[1-3,5]		Significant improvement with MYOBLOC **at Week 4** in doses tested (secondary endpoint)[4]

Abbreviations: CD, cervical dystonia; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

PROVEN FIRST-LINE TREATMENT FOR CD

Toxin-Naïve Patients Head-to-Head Study: MYOBLOC vs. BOTOX®[6]

Noninferiority of MYOBLOC vs. BOTOX was established[6]
Mean Change (Improvement), Baseline to Week 4*



*Per-protocol population.
†Not statistically significant.

- **TWSTRS-total score and TWSTRS-pain scores** were numerically greater with MYOBLOC than BOTOX, but this difference was not statistically significant[6]
- No significant difference in median duration of clinical effect[6]

Study 402: A randomized, double-blind, multicenter, noninferiority trial (N=93) comparing the efficacy, safety, and duration of effect of BOTOX with MYOBLOC in toxin-naïve patients with CD.[6] Two dose arms were studies: BOTOX 150 Units (n=47) or MYOBLOC 10,000 Units (n=46).

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)

Please refer to the full Prescribing Information, including Boxed WARNING, and additional Important Safety Information on next page.

DEMONSTRATED TOLERABILITY[1]

Most commonly reported adverse reactions in >5% of MYOBLOC-treated patients at any dose and >5% more common than placebo (Studies 1, 2, and 4)[1]

Adverse Reaction	MYOBLOC (%)			PLACEBO (%)
	2,500 Units (N=31)	5,000 Units (N=67)	10,000 Units (N=106)	(N=104)
Dry Mouth	3	12	34	3
Dysphagia	16	10	25	3
Injection-site pain	16	12	15	9
Headache	10	16	11	8

FLEXIBLE DOSING AND ADMINISTRATION

3 single-dose vial sizes*

*For single-patient use.

READY TO USE AND REQUIRES NO MIXING[1]

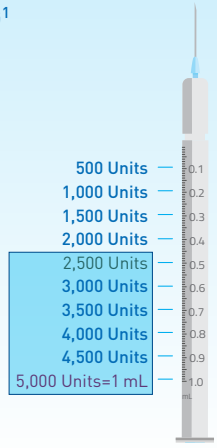
Dosing Considerations

- Cervical dystonia symptom severity
- Risk of swallowing or breathing difficulties in patients with neuromuscular disorders[1]
- Patient weight and muscle bulk

Dosing Recommendations

Recommended initial total dose divided among affected muscles[1]:

- Patients with a prior history of tolerating botulinum toxin injections is 2,500 to 5,000 Units
- 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 response



Learn more about how your patients may benefit from MYOBLOC at MYOBLOChcp.com.

IMPORTANT SAFETY INFORMATION (cont'd)

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 Prescribing Information, including Boxed WARNING, and additional Important Safety Information on next page.

If you have adult patients like Lydia in your practice, scan QR code to request samples or visit MYOBLOChcp.com

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.
  - **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 post-marketing 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.

- **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

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. Use of anticholinergic drugs after administration of MYOBLOC may potentiate systemic anticholinergic effects. 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. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of MYOBLOC.

Please refer to the full Prescribing Information, including Boxed WARNING.

References:
1. MYOBLOC. Prescribing Information. Solstice Neuroscience, LLC. **2.** Brashear A, Lew MF, Dykstra DD, et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-responsive cervical dystonia. *Neurology.* 1999;53(7):1439-1446. doi:10.1212/wnl.53.7.1431 **3.** Brin MF, Lew MF, Adler CH, et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. *Neurology.* 1999;53(7):1431-1438. doi:10.1212/wnl.53.7.1431 **4.** Lew MF, Adornato BT, Duane DD, et al. Botulinum toxin type B: a double-blind, placebo-controlled, safety and efficacy study in cervical dystonia. *Neurology.* 1997;49(3):701-707. doi:10.1212/wnl.49.3.701 **5.** Data on file. Solstice Neurosciences, LLC. **6.** Pappert EJ, Germanson T. NeuroBloc botulinum toxin type B vs type A in toxin-naive patients with cervical dystonia: randomized, double-blind, non-inferiority trial. *Mov Disord.* 2008;23(4):510-517. doi:10.1002/mds.21724

Supernus® Pharmaceuticals

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