CHRONIC SIALORRHEA PATIENT PROFILE

MEET DONNA*

AGE: 68

HISTORY:

- Diagnosed with Parkinson's disease at age 62; current medication: carbidopa/levodopa 25 mg/100 mg, 5 times a day
- Over the past 6 months, drooling while speaking, eating, and drinking worsened, and now sometimes impacts her social engagements
- Donna assumes the drooling is a natural part of the progression of Parkinson's disease

EXAMINATION:

- Mild drooling and chapped lips
- When asked about feeling embarrassed about excess saliva or drooling, Donna admitted she has felt self-conscious

DIAGNOSIS:

Chronic sialorrhea (CS)

CLINICIAN RESPONSE:

Prompted by their discussion, Donna's healthcare provider has decided it's time to start treating Donna's CS

Do you have patients like Donna 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 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.

Please see the full Prescribing Information and additional Important Safety Information on next page.

Consider making MYOBLOC your first choice of treatment

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

SIGNIFICANT IMPROVEMENT IN USFR AND CGI-C[1,2]

At Week 4, MYOBLOC 2,500 U and 3,500 U achieved:

56% **REDUCTION IN USFR**
from baseline vs. 11% with placebo
(-.37 and -.36 vs. -.07, respectively; *P*<0.0001)

According to CGI-C* scores at Week 4 post-injection:

Nearly **60%** of patients taking MYOBLOC 2,500 U or 3,500 U were much, or very much, improved

*The CGI-C is a 7-point scale ranging from a score of 1, "very much improved," to a score of 7, "very much worse."

IMPROVEMENTS AS EARLY AS 1 WEEK THAT MAY BE MAINTAINED FOR OVER 1 YEAR[1,2]

In the phase 3 open-label extension study, improvement was maintained with subsequent dosing of MYOBLOC 3,500 U for over 1 year

*Mean USFR change from baseline (g/min) at Week 1 for MYOBLOC 2,500 was -0.2 (*P* vs. placebo=0.0045); MYOBLOC 3,500, -0.3; (*P* vs. placebo<0.0001); and placebo, -0.08.

†Mean USFR change from baseline (g/min) at Week 8 for MYOBLOC 2,500 was -0.28 (*P* vs. placebo<0.0001); MYOBLOC 3,500, -0.34; (*P* vs. placebo<0.0001); and placebo, -0.09.

‡Mean USFR change from baseline (g/min) at Week 13 for MYOBLOC 2,500 was not significant; MYOBLOC 3,500, -0.18; (*P* vs. placebo=0.0056); and placebo, -0.07.

Study 1

Part A: Phase 3, multicenter, randomized, double-blind, placebo-controlled, single-treatment study (N=187) to determine the efficacy, safety, and tolerability over a 13-week period. Adult patients with chronic, troublesome sialorrhea for ≥3 months received MYOBLOC 2,500 U (n=63) or 3,500 U (n=64), or placebo (n=57), and co-primary efficacy measures were USFR and CGI-C at Week 4[1,2]

Part B: Phase 3, open-label, multiple-treatment extension study (N=170) to assess duration of efficacy, safety, and tolerability over a maximum of 65 weeks. Patients received up to 4 additional treatment sessions over 1 year[2]

Abbreviations: CGI-C, Clinical Global Impression of Change; USFR, Unstimulated Salivary Flow Rate.

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

MYOBLOC HAS DEMONSTRATED TOLERABILITY[1]

Studies 1 and 2: Adverse reactions in at least 5% of MYOBLOC-treated patients and greater than placebo in pooled chronic sialorrhea studies

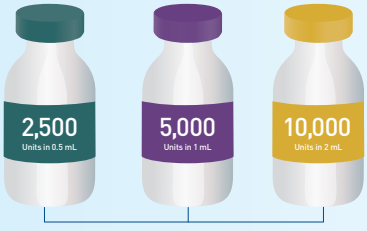
Adverse Reaction	MYOBLOC (%)			PLACEBO (%)
	1,500 U (N=14)*	2,500 U (N=75)†	3,500 U (N=77)†	(N=75)
Dry mouth	**14**	**36**	**39**	**7**
Dental caries	0	7	5	3
Dysphagia	0	9	4	3

1 patient discontinued due to dry mouth

*Adverse reactions for the 1,500 Unit dose were only evaluated in Study 2.
†Adverse reactions for the 2,500 Unit and 3,500 Unit doses were evaluated in Studies 1 and 2.

Study 2 was a Phase 2, multicenter, double-blind, placebo-controlled, sequential dose-escalation study (N=54) to assess the efficacy, safety, and tolerability of MYOBLOC for the treatment of sialorrhea of ≥3 months duration in patients with Parkinson's disease.[1,3] Dose arms were MYOBLOC 1,500 U (n=14), 2,500 U (n=12), or 3,500 U (n=13) vs. matching placebo (n=15); the primary efficacy measure was change in the Drooling Frequency and Severity Scale (DFSS) at Week 4, and secondary efficacy measures were changes in DFSS at Week 12 and in USFR at Weeks 4 and 12[1,3]

MYOBLOC IS READY TO USE AND REQUIRES NO MIXING[1]



3 Single-dose vial sizes*

*For single-patient use.

1,500-3,500 U is the recommended dose range divided among the parotid and submandibular glands; 500 Units to 1,500 Units per parotid gland and 250 Units per submandibular gland; no more frequent than every 12 weeks

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

Have you identified patients in your practice like Donna who may benefit from MYOBLOC? Request samples by scanning the QR code 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.

  – **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 see the full Prescribing Information, including Boxed WARNING.

References:

1. MYOBLOC. US Prescribing Information. Solstice Neurosciences, LLC. **2.** Data on file. Supernus Pharmaceuticals, Inc. **3.** ClinicalTrials.gov. NCT00515437: A Multi-Center Study of MYOBLOC for the Treatment of Sialorrhea in Parkinson's Disease Patients. Accessed April 29, 2022. https://clinicaltrials.gov/ct2/show/NCT00515437

Supernus® Pharmaceuticals

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