CHRONIC SIALORRHEA PATIENT PROFILE

MEET CHARLES*

AGE: 72

HISTORY:

- Diagnosed with Parkinson's disease at age 64 and chronic sialorrhea 2 years ago
- Current medication: levodopa/carbidopa, 25 mg/100 mg, 6 times a day; benztropine (anticholinergic), 3 times a day
- Charles continues to experience difficulties speaking
- His partner has noted wetting on his pillow and clothing

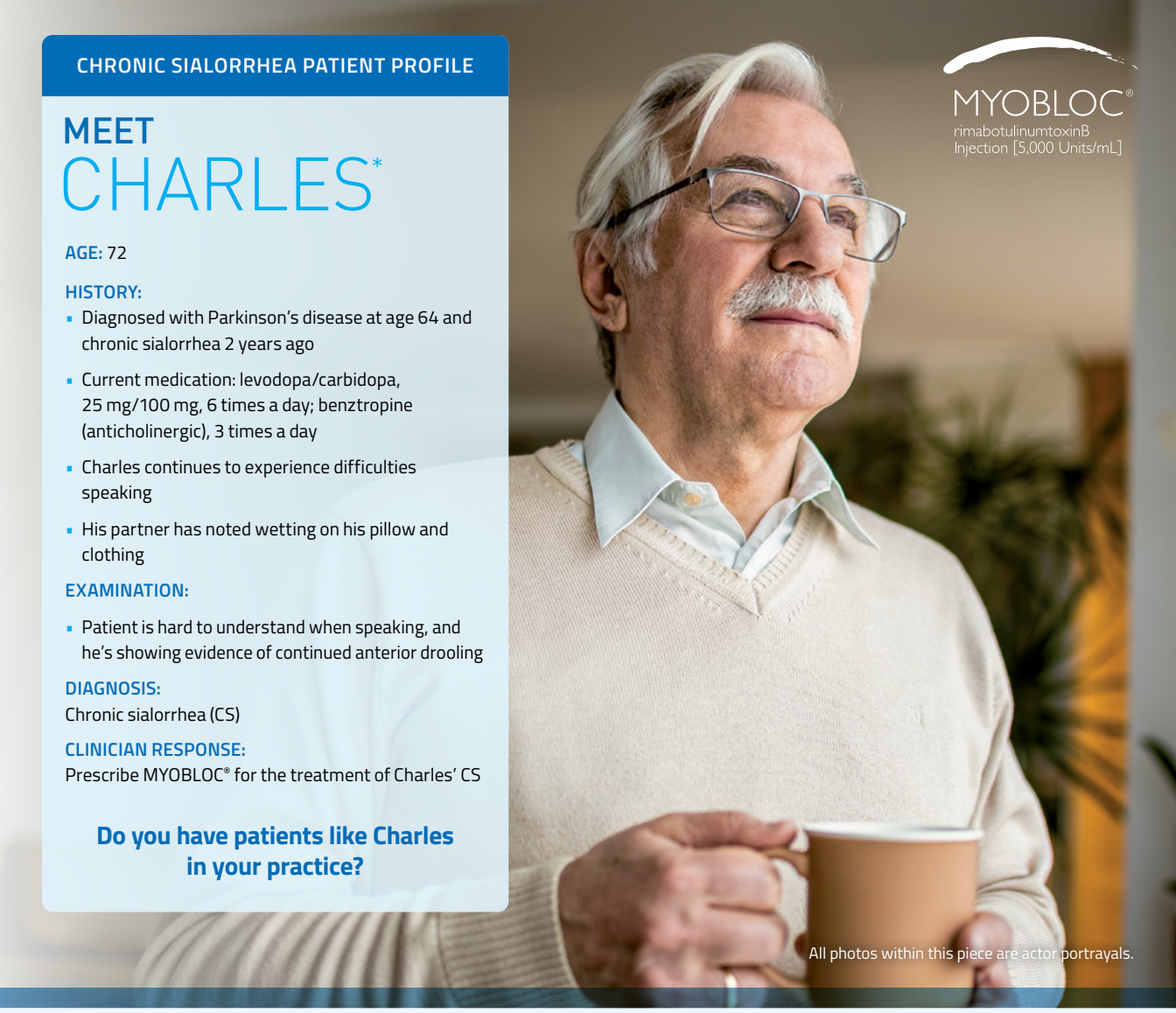
EXAMINATION:

- Patient is hard to understand when speaking, and he's showing evidence of continued anterior drooling

DIAGNOSIS:
Chronic sialorrhea (CS)

CLINICIAN RESPONSE:
Prescribe MYOBLOC® for the treatment of Charles' CS

Do you have patients like Charles in your practice?



*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 MYOBLOC your treatment of choice for patients like Charles

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

OTHER TREATMENT OPTIONS FOR THE MANAGEMENT OF CS[1,2]

Non-invasive

Oral pharmacologic

Surgical

Botulinum toxin may be an effective first-line approach to managing CS for appropriate patients[3,4]

MYOBLOC PROVIDED SIGNIFICANT IMPROVEMENT IN USFR AND CGI-C AT WEEK 4 IN PATIENTS WITH CS*[3]

MYOBLOC has demonstrated early and durable improvements in CS[3,5]

SIGNIFICANT SYMPTOM RELIEF WAS SEEN as early as **WEEK 1‡**

CONTINUED through **WEEK 13§**

MAINTAINED for over **1 YEAR‖**

*Mean USFR change from baseline (g/min) at Week 4 for MYOBLOC 2,500 was -0.37†; MYOBLOC 3,500, -0.36†; and placebo, -0.07. CGI-C score at Week 4 for MYOBLOC 2,500 was 2.38†; MYOBLOC 3,500, 2.45†; and placebo, 3.59. (†*P*<0.0001).

‡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 13 for MYOBLOC 2,500 was not significant; MYOBLOC 3,500, -0.18 (*P* vs. placebo=0.0056); and placebo, -0.07.

‖Maintenance required subsequent dosing of 3,500 U.

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[3,5]

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[5]

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 last page.

MYOBLOC HAS DEMONSTRATED TOLERABILITY[3]

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

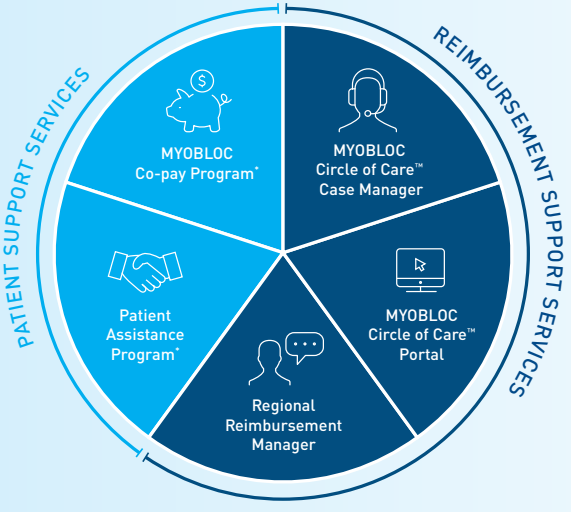
1 patient discontinued due to dry mouth

*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.[3,6] 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 DFSS at Week 4, and secondary efficacy measures were changes in DFSS at Week 12 and in USFR at Weeks 4 and 12[3,6]

Abbreviation: DFSS, Drooling Frequency & Severity Scale.

WITH MYOBLOC, YOU AND YOUR PATIENTS ARE SURROUNDED BY SUPPORT



Eligible patients may receive up to $4,000 each year to help with out-of-pocket expenses

*Eligibility requirements apply. For program terms and conditions, please visit **www.MYOBLOC.com**.

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

Have any patients like Charles who may benefit from MYOBLOC? Request samples or learn more about injection training by scanning the QR code or visiting 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.
- **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. Hockstein NG, Samadi DS, Gendron K, Handler SD. Sialorrhea: a management challenge. *Am Fam Physician.* 2004;69(11):2628-2634. **2.** Varley LP, Denieffe S, O'Gorman C, Murphy A, Gooney M. A systematic review of noninvasive and invasive sialorrhoea management. *J Clin Nurs.* 2019;28(23-24):4190-4206. **3.** MYOBLOC. US Prescribing Information. Solstice Neurosciences, LLC. **4.** Isaacson J, Patel S, Torres-Yaghi Y, Pagán F. Sialorrhea in Parkinson's disease. *Toxins (Basel).* 2020;12(11):691. **5.** Data on file. Supernus Pharmaceuticals, Inc. **6.** 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]