

Service & Support

1-888-461-2255

8:00 AM - 7:00 PM Eastern Time Monday-Friday

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www.myobloc.com

Distant Spread of Toxin Effect

Postmarketing reports indicate that 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 may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. 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 treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses. (See WARNINGS, PRECAUTIONS, and OVERDOSE sections of full Prescribing Information).

Important Safety Information

Myobloc® (rimabotulinumtoxinB) Injection is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. Units of biological activity of MYOBLOC cannot be compared to or converted into units of any other botulinum toxin products.

Before administering MYOBLOC, physicians should consult the full Prescribing Information and Medication Guide. Note to representatives: Please provide full Prescribing Information and Medication Guide when presenting this material.

The most frequently reported adverse events with MYOBLOC are dry mouth, dysphagia, dyspepsia, and injection site pain. The vast majority of these adverse events were mild to moderate, temporary, self-resolving, and more common with higher doses. These adverse events may occur within the first week following treatment and may have a duration of several months. In controlled clinical trials, few patients (<1%) stopped treatment due to dry mouth or dysphagia. There is a reduced frequency of dry mouth and dysphagia reported with continued treatment. Dysphagia has commonly been reported by patients treated with all botulinum toxins for cervical dystonia.

Caution should be exercised when administering MYOBLOC to individuals with motor neuron disease (eg, amyotrophic lateral sclerosis), peripheral motor neuropathic diseases (eg, motor neuropathy) or neuromuscular junctional disorders (eg, myasthenia gravis or Lambert-Eaton syndrome). These patients may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of MYOBLOC. In these patients, rare cases of dysphagia severe enough to cause aspiration pneumonia or to warrant the insertion of a gastric feeding tube have also been reported.

Coadministration of MYOBLOC and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated.



MYOBLOC®

rimabotulinumtoxinB
Injection [5,000 Units/mL]

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For more information about our Reimbursement Services and Patient Assistance Programs, or to obtain application forms, please call

1-888-461-2255 or visit our Web site at

www.myobloc-reimbursement.com

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