

When requesting Myobloc® (rimabotulinumtoxinB), the individual requiring treatment must be diagnosed with the following FDA-approved indication or approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

- Myobloc® (rimabotulinumtoxinB) 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.

Approved Off-label Compendial uses

- Overactive bladder
- Excessive salivation

Coverage Guidelines

For all approved indications, the individual must meet ALL of the following criteria for approval:

- Does not have hypersensitivity to any botulinum toxin product or excipients
- Does not have an infection at the proposed injection site
- Is 18 years of age or older

For excessive salivation, the condition must be associated with Parkinsonism

Approval duration: 12 months

Additional Information for Prescribers

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Potency units of Myobloc® (rimabotulinumtoxinB) are not interchangeable with other preparations of botulinum toxin products
- 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.
- Myobloc® (rimabotulinumtoxinB) contains albumin, a derivative of human blood. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

References

1. Myobloc[®] prescribing information. South San Francisco, CA: Solstice Neurosciences, Inc.: May2010. http://www.myobloc.com/hp_about/PI_5-19-10.pdf. Accessed February 28, 2017.
2. Klasco RK (Ed): DRUGDEX[®] System. Thomson Micromedex, Greenwood Village, CO. Accessed February 28, 2017. <http://www.micromedexsolutions.com>

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