BOTOX® reconstitution and dilution procedures

BOTOX® (onabotulinumtoxinA) is supplied in convenient, secure, single-use, 100-Unit and 200-Unit vials

- Vials designed for maximum extraction

Always be sure you've received actual BOTOX® (onabotulinumtoxinA) neurotoxin product from Allergan:

- To ensure product authenticity look for the holographic film on the vial; "Allergan" should appear within rainbow lines
- If you do not see the rainbow lines or if "Allergan" does not appear, do not use the product, and please contact Allergan directly

Each single-use vial contains 100 U or 200 U of vacuum-dried *Clostridium botulinum* type A neurotoxin complex. Prior to intramuscular injection, reconstitute vacuum-dried BOTOX® product only with sterile, nonpreserved, normal saline (0.9% sodium chloride injection).

Dilution Table

Dilution added to **200-Unit** vial (0.9% sodium chloride injection)	Resulting dose (Units per 0.1 mL)	Dilution added to **100-Unit** vial (0.9% sodium chloride injection)	Resulting dose (Units per 0.1 mL)
1.0 mL	**20.0 U**	**1.0 mL**	**10.0 U**
2.0 mL	**10.0 U**	**2.0 mL**	**5.0 U**
4.0 mL	**5.0 U**	**4.0 mL**	**2.5 U**
8.0 mL	**2.5 U**	**8.0 mL**	**1.25 U**
10.0 mL	**2.0 U**	**10.0 mL**	**1.0 U**

These dilutions are calculated for an injection volume of 0.1 mL. A decrease or increase in the BOTOX® dose is also possible by administering a smaller or larger injection volume—from 0.05 mL (50% decrease in dose) to 0.15 mL (50% increase in dose).

Note: The product and diluent do not contain a preservative. Administer the 200-Unit vial of BOTOX® within 4 hours, or the 100-Unit vial within 24 hours after reconstitution. During this time, BOTOX® solution should be stored in a refrigerator at 2°C to 8°C.

Using the reconstitution needle, draw up the proper amount of saline (see Dilution Table) in the appropriately sized sterile syringe. A 21-gauge, 1½-inch or 2-inch needle is recommended for reconstitution. Reconstituted BOTOX® should be clear, colorless, and free of particulate matter.

Insert the needle straight into the vial, then tilt the vial at a 45° angle. Slowly inject the saline into the BOTOX® neurotoxin vial. Vacuum is present in the vial, which demonstrates that the sterility of the vial is intact. Do not use the vial if the vacuum does not pull the saline into the vial.

Release the vacuum by disconnecting the syringe from the needle and allowing air to flow into the vial. Gently mix BOTOX® with the saline by moving vial side to side or rotating the vial.

Draw the fluid into the injection syringe by placing the needle into the bottom corner of the vial for full extraction.

Disconnect the injection syringe from the vial and attach an appropriate needle for injection. A 25-, 27-, or 30-gauge needle may be used for superficial muscles, and a longer 22-gauge needle may be used for deeper musculature.

Indication

BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

IMPORTANT SAFETY INFORMATION

Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of BOTOX® 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 adults 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.

Please see additional Important Safety Information about BOTOX® on reverse side.

BOTOX® onabotulinumtoxinA

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

WARNINGS

The recommended dosage and frequency of administration for BOTOX® should not be exceeded. Risks resulting from administration at higher dosages are not known.

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX® cannot be compared to or converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Spread of Toxin Effect

Postmarketing safety data from BOTOX® and other approved botulinum toxins suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection. The symptoms are consistent with the mechanism of action of botulinum toxin and 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 related to spread of toxin effects. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, and 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, symptoms consistent with spread of toxin effect have been reported at doses comparable to or lower than doses used to treat cervical dystonia.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, urticaria, soft-tissue edema, and dyspnea.

Pre-Existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (eg, 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 BOTOX®.

ADVERSE REACTIONS

General

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin.

There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

Cervical Dystonia

The most frequently reported adverse reactions following injection of BOTOX® for cervical dystonia include dysphagia (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

Overdosage

Excessive doses of BOTOX® may be expected to produce neuromuscular weakness with a variety of symptoms. Respiratory support may be required where excessive doses cause paralysis of respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis.

In the event of suspected or actual overdosage, please contact your local or state health department to process a request for antitoxin through the Centers for Disease Control and Prevention (CDC). If you do not receive a response within 30 minutes, please contact the CDC directly at 1-770-488-7100.

Please see accompanying full prescribing information including Medication Guide.

BOTOX® onabotulinumtoxinA