

The following supplies will be needed prior to beginning the reconstitution procedure:



- One 200-Unit vial of BOTOX® (onabotulinumtoxinA)
- One 21-gauge, 2-inch needle (for reconstitution)
- One 5-mL syringe
- Four 1-mL tuberculin syringes (for injection)
- At least four 30-gauge, 0.5-inch needles (for injection)
- One 10-mL single-use vial of preservative-free, 0.9% sodium chloride (saline)
- Alcohol swabs for cleaning the rubber stoppers on the saline and BOTOX® vials
- Gauze pads
- 1 pair of gloves
- Hazardous medical waste container

Ensure you have received authentic BOTOX® from Allergan®. Look for the holographic film on the vial; “Allergan®” should appear within the rainbow lines.



IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX® should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX® (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties

Treatment with BOTOX® 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 oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

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 also 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.

IMPORTANT SAFETY INFORMATION (continued) ADVERSE REACTIONS

Adverse reactions to BOTOX® for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Chronic Migraine

The most frequently reported adverse reactions following injection of BOTOX® for Chronic Migraine include neck pain (9%), headache (5%), eyelid ptosis (4%), migraine (4%), muscular weakness (4%), musculoskeletal stiffness (4%), bronchitis (3%), injection-site pain (3%), musculoskeletal pain (3%), myalgia (3%), facial paresis (2%), hypertension (2%), and muscle spasms (2%).

Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX® are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

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.

DRUG INTERACTIONS

Co-administration of BOTOX® and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin 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. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX®.

For more information on BOTOX®, please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

References: 1. Blumenfeld A, Silberstein SD, Dodick DW, Aurora SK, Turkel CC, Binder WJ. Method of injection of onabotulinumtoxinA for chronic migraine: a safe, well-tolerated, and effective treatment paradigm based on the PREEMPT clinical program. *Headache*. 2010;50(9):1406-1418. 2. BOTOX® Prescribing Information, February 2021.



BOTOX® and its design are registered trademarks of Allergan, Inc., an AbbVie company. © 2021 AbbVie. All rights reserved. BOTOXMedical.com/ChronicMigraine 1-800-44-BOTOX BCM70138-v7 03/21 009475



BOTOX®
onabotulinumtoxinA injection



Reconstitution/Injection Pocket Card

This pocket card is a reference guide for BOTOX® (onabotulinumtoxinA) injection sites for Chronic Migraine patients. The reconstitution materials, dilution table, and Injection Paradigm are highlighted for quick reference.

Indication Chronic Migraine

BOTOX® for injection is indicated for the prophylaxis of headaches in adult patients with Chronic Migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

Limitations of Use

Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in 7 placebo-controlled studies.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: 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, 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 an underlying condition that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat Cervical Dystonia and spasticity and at lower doses.

Please see additional Important Safety Information about BOTOX® inside.

BOTOX[®] Injection Sites and Order of Injection

0.1 mL (5 Units) of BOTOX[®] per site^{1,2,*}

	Dilution	
	Saline added (0.9% sodium chloride injection)	Resulting BOTOX [®] dose (Units per 0.1 mL)
100-Unit Vial	2 mL	5 Units
200-Unit Vial	4 mL	5 Units

Resulting concentration is 5 Units per 0.1 mL.

- Upon completion of reconstitution, you will have 4 tuberculin syringes, each with 1 mL of BOTOX[®] and a 30-gauge, 0.5-inch needle attached

Order	Muscle	Total Recommended Dosage ²
A	Corrugator ^b	10 Units divided in 2 sites
B	Procerus	5 Units in 1 site
C	Frontalis ^b	20 Units divided in 4 sites
D	Temporalis ^b	40 Units divided in 8 sites
E	Occipitalis ^b	30 Units divided in 6 sites
F	Cervical paraspinals ^b	20 Units divided in 4 sites
G	Trapezius ^b	30 Units divided in 6 sites
Total Dose		155 Units divided in 31 sites

¹Each intramuscular (IM) injection site = 0.1 mL = 5 Units of BOTOX[®].

²Dose distributed bilaterally.

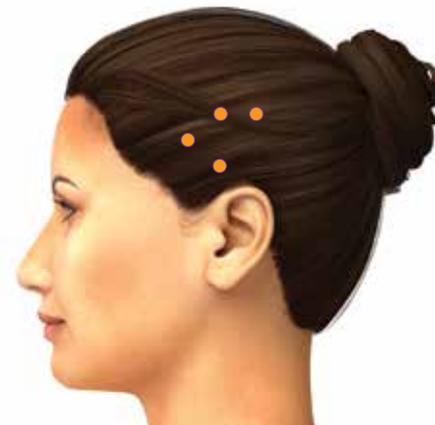
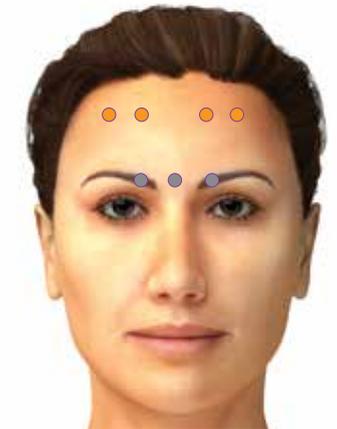
A. Corrugator
10 Units divided in 2 sites



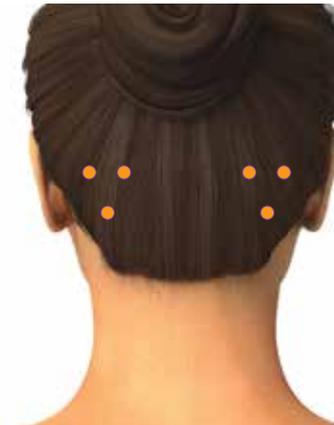
B. Procerus
5 Units in 1 site



C. Frontalis
20 Units divided in 4 sites



D. Temporalis
40 Units divided in 8 sites



E. Occipitalis
30 Units divided in 6 sites



F. Cervical paraspinals
20 Units divided in 4 sites



G. Trapezius
30 Units divided in 6 sites

The dosing and administration of BOTOX[®] is a detailed process. The information on this page contains highlights only and is not meant to be a substitute for appropriate training or review of full Prescribing Information.

*The recommended dilution is 200 Units/4 mL or 100 Units/2 mL, with a final concentration of 5 Units per 0.1 mL (see Sections 2.1 and 2.2 of the full Prescribing Information for preparation and dilution techniques and additional dosing information).

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX[®] is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Spread of Toxin Effect

See Boxed Warning.

No definitive serious adverse event reports of distant spread of toxin effect associated with BOTOX[®] for Chronic Migraine at the labeled dose have been reported.

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 nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

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