

# Surrounded by BOTOX® support

Whether you're new to BOTOX® or an experienced injector, AbbVie offers a suite of educational resources for your practice and your appropriate Chronic Migraine patients

# GET TRAINE



A range of injection training options, including in-office preceptorships/ proctorships, virtual/online training programs, and interactive hands-on cadaver lab instruction to answer specific BOTOX® questions.



Visit BOTOXONE.com for injection, reconstitution, and anatomy resources to help your patients access treatment sooner.



## Customized assistance

Additional practice with an in-office CaMILE\* injection simulator and live injection observations as you gain comfort with the PREEMPT<sup>†</sup> Protocol.

# *GET STARTED*



Register with ONE TOUCH by calling 1-800-44-BOTOX (26869).<sup>‡</sup>

<sup>‡</sup>This number serves patients and healthcare providers. Please follow the healthcare provider prompts (press 2)



# purchasing

Acquire BOTOX® via Buy & Bill or Specialty Pharmacy.

GET GOING



# **Streamlined** orderina

Upon opening an account, you will be approved to place the first order immediately, with 90-day terms for payment.§

§Other terms and conditions apply.



AbbVie provides resources and in-office support that may help streamline BOTOX® office processes, including reimbursement support, product acquisition, prior authorization, and re-treatment. Talk to your Account Specialist to learn more.

\*CaMILE = Chronic Migraine Injection Learning Experience



# savings

Eligible, commercially insured patients may pay as little as \$0 for treatment with the BOTOX® Savings Program."

"Eligibility: Available to patients with commercial insurance coverage for BOTOX" who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Control C of Defense, or Veterans Affairs programs; or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. For full Terms and Conditions visit abbv.ie/bsp-terms or call 1-800-44-B0TOX for additional information. To learn about AbbVie's privacy practices and you privacy choices, visit https://abbv.ie/corpprivacy



# **Available** sample program

Talk to your AbbVie Account Specialist or request to have one reach out to you at https://www.botoxone.com /request-a-rep to learn about a sample program that allows you to evaluate the efficacy and safety of treatment in appropriate new BOTOX® Chronic Migraine patients.

\*PREEMPT = Phase 3 REsearch Evaluating Migraine Prophylaxis Therapy.

BOTOX® (onabotulinumtoxinA) 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).

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, dysphonia, 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 approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and



## 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.

## 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 preexisting 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 Preexisting 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 *Wamings and Precautions*).

## **Dysphagia and Breathing Difficulties**

Treatment with BOTOX and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with preexisting 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.

#### ADVERSE REACTIONS

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

## **Chronic Migraine**

The most frequently reported adverse reactions following injection of BOTOX for chronic migraine vs placebo include, respectively, neck pain (9% vs 3%); headache (5% vs 3%); eyelid ptosis (4% vs <1%); migraine (4% vs 3%); muscular weakness (4% vs <1%); musculoskeletal stiffness (4% vs 1%); bronchitis (3% vs 2%); nijectionsite pain (3% vs 2%); musculoskeletal pain (3% vs 1%); myalgia (3% vs 1%); facial paresis (2% vs 0%); hypertension (2% vs 1%); and muscle spasms (2% vs 1%).

#### 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.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide, or visit https://rxabbvie.com/pdf/botox\_pi.pdf

