BOTOX® (onabotulinumtoxinA) Treatment Record for Chronic Migraine Patients

Indication for 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).

Important Limitations
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.

Patient Name: _____ DOB: ____ / ____ / ____

Treatment Date: ____ / ____ / ____ Weeks since last treatment (if applicable): _____

Number of headache days/month—Current: _____ Baseline (if applicable): _____

Number of headache hours/day—Current: _____ Baseline (if applicable): _____

(When determining number of headache days, it may be beneficial to ask the patient how many headache-free days each month the patient is experiencing.)

Clinical rationale for BOTOX®: _____

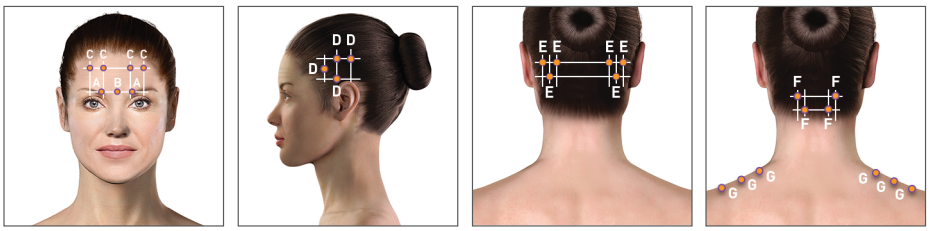
Vial Size/NDC No. **200 Unit Vial/NDC No.: 00023-3921-02**[a] **100 Unit Vial/NDC No.: 00023-1145-01**[a]

Dilution (200 Units/4 mL or 100 Units/2 mL)	Lot number(s)	Vial expiration date(s)

☐ **Please check box if an SPP is used.**

[a]For electronic billing, payers require an 11-digit NDC number [5-4-2 configuration] to be reported on the claim form. Therefore, an additional zero should be added to the beginning of the 10-digit NDC listed on the box [eg, 00023-3921-02].

BOTOX® Dosing by Muscle Areas for Chronic Migraine



A. Corrugator
BOTOX® dosage: 10 Units divided in
2 sites Right: ____ Left: ____

B. Procerus
BOTOX® dosage: 5 Units in
1 site _____

C. Frontalis
BOTOX® dosage: 20 Units divided in
4 sites Right: ____ Left: ____

D. Temporalis
BOTOX® dosage: 40 Units divided in
8 sites Right: ____ Left: ____

E. Occipitalis
BOTOX® dosage: 30 Units divided in
6 sites Right: ____ Left: ____

F. Cervical Paraspinal
BOTOX® dosage: 20 Units divided in
4 sites Right: ____ Left: ____

G. Trapezius
BOTOX® dosage: 30 Units divided in
6 sites Right: ____ Left: ____

Total Units injected: _____ Total Units discarded: _____

Physician signature: _____

Please document patient response on reverse side

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, including spasticity in children, 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 on reverse side.

Documenting Treatment Outcomes: Re-treatment Criteria	*Current*	*Reduction from Baseline*
Number of headache days post-treatment *(When determining number of headache days, it may be beneficial to ask the patient how many headache-free days each month the patient is experiencing.)*		
☐ Moderate or severe pain intensity ☐ Nausea ☐ Vomiting ☐ Photophobia ☐ Phonophobia ☐ Unilateral ☐ Pulsating		
	Current	
Disability due to headache/migraine (eg, work, school)?		
Reduction of ER visits post-treatment?		

Physician signature: _____

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX® (onabotulinumtoxinA) 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 AND PRECAUTIONS

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.

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.

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, 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.

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
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® or 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 and also by administration of a muscle relaxant before or after administration of BOTOX®.

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

Allergan