

BOTOX[®] for Chronic Migraine

Treatment Considerations and Live Patient Injections



PROGRAM OVERVIEW:

- Expert clinical discussion focusing on:
 - Chronic Migraine disease state and definition
 - BOTOX[®] injection paradigm review
 - Tips for identifying Chronic Migraine patients and setting treatment expectations



You can also access BOTOX[®] resources and information online at any time.

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Friday, July 14, 2017 at 4:30 – 7:30PM

FACULTY

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LOCATION

Disney's Grand Floridian Resort
Room: Salon 8
4401 Floridian Way
Lake Buena Vista, FL 32830

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Once registered, you will receive an e-mail confirmation containing contact information and program logistics.

Space is limited, please register by July 9, 2017 to reserve your participation in this popular program.

Questions? Please contact your local field representative.

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 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.

Please see next page for additional IMPORTANT SAFETY INFORMATION.

BOTOX[®] (onabotulinumtoxinA) Important Information

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).

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.

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.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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 (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular 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. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

The following adverse reactions to BOTOX[®] for injection are discussed in greater detail in the following sections: Spread of Toxin Effect (see *Boxed Warning*); Serious Adverse Reactions with Unapproved Use (see *Warnings and Precautions*); Hypersensitivity Reactions (see *Contraindications and Warnings and Precautions*); Increased Risk of Clinically Significant Effects with Pre-Existing Neuromuscular Disorders (see *Warnings and Precautions*); and Dysphagia and Breathing Difficulties (see *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%).

Post Marketing 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[®] and aminoglycosides or other agents interfering with neuromuscular transmission (e.g. 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 the accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

Allergan speaker programs adhere to applicable federal and state laws and regulations, including all disclosure requirements. This invitation is not extended to practitioners licensed in certain states and where otherwise prohibited by law. Attendees do have the ability to opt out of the meal portion of the program and attend the presentation.

Pursuant to applicable healthcare guidelines and codes this program is open to healthcare professionals only. Spouses and/or guests may not participate in the meeting or associated meals. We appreciate your understanding and support of our commitment to following the highest ethical standards as related to interactions with healthcare professionals.