BOTOX® (onabotulinumtoxinA) Treatment Record for Blepharospasm

Patient name: _____

Clinical rationale for BOTOX® injection: _____

Response prior to BOTOX® treatment: _____

Comments: _____

Dilution Table

200-Unit Vial		100-Unit Vial	
Diluent to Add (0.9% Sodium Chloride Injection Only)	Resulting Dose (Units per 0.1 mL)	Diluent to Add (0.9% Sodium Chloride Injection Only)	Resulting Dose (Units per 0.1 mL)
1 mL	20 Units	1 mL	10 Units
2 mL	10 Units	2 mL	5 Units
4 mL	5 Units	4 mL	2.5 Units
8 mL	2.5 Units	8 mL	1.25 Units
10 mL	2 Units	10 mL	1 Unit

Treatment date _____

Dilution (Units/mL) _____

Lot number(s) _____

Vial expiration date(s) _____

Note: 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). BOTOX® should only be reconstituted in preservative-free 0.9% sodium chloride injection, USP. Because the product and diluent do not contain a preservative, use within 24 hours once opened and reconstituted. During the 24 hours, BOTOX® solution should be stored in a refrigerator at 2ºC to 8ºC.

Indication

Blepharospasm

BOTOX® for injection is indicated for the treatment of Blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.

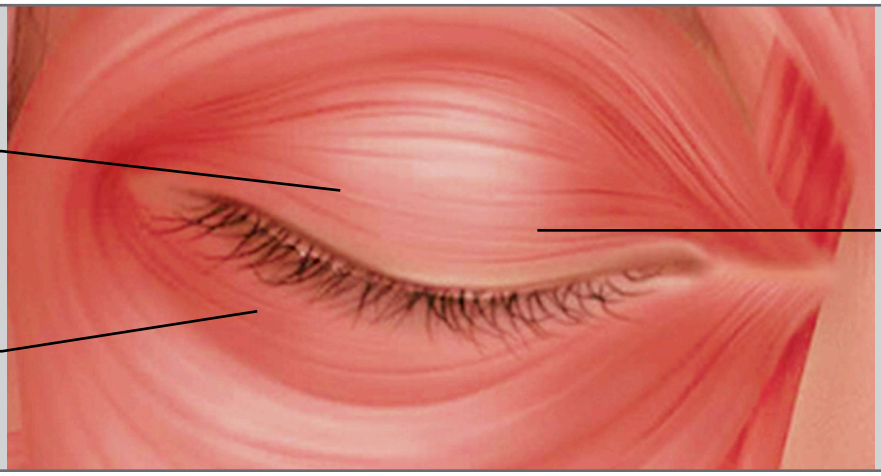
IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

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® on following pages.

Patient injection record (fill in number of Units injected)



Note: These are general areas, not the specific injection sites.

Record injection location and dose			
Muscle Injected	**Right** (Units/Injection)	**Left** (Units/Injection)	**Total** (Units/Muscle)
Upper lid			
Medial pretarsal orbicularis oculi			
Lateral pretarsal orbicularis oculi			
Lower lid			
Lateral pretarsal orbicularis oculi			

Total Units injected: _____ Total Units discarded: _____

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

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 Blepharospasm at the recommended dose (30 Units and below) have been reported.

Please see additional Important Safety Information about BOTOX® on following pages.

Blepharospasm dosing information

- For blepharospasm, reconstituted BOTOX® (onabotulinumtoxinA) is injected using a sterile, 27- to 30-gauge needle without electromyographic guidance
- The initial recommended dose is 1.25 Units to 2.5 Units (0.05 mL-0.1 mL volume at each site) injected into the medial and lateral pretarsal orbicularis oculi of the upper lid and into the lateral pretarsal orbicularis oculi of the lower lid
- Avoiding injection near the levator palpebrae superioris may reduce the complication of ptosis. Avoiding medial lower lid injections, and thereby reducing diffusion into the inferior oblique, may reduce the complication of diplopia. Ecchymosis can be prevented by applying pressure at the injection site immediately after the injection
- In general, the initial effect of the injections is seen within 3 days, and the peak effect occurs at 1 to 2 weeks post treatment. Treatment effects last approximately 3 months, following which the procedure can be repeated
- The dose may be increased up to twofold if the response from the initial treatment is considered insufficient (ie, defined as an effect that does not last longer than 2 months). However, there appears to be little benefit obtainable from injecting more than 5 Units per site
- The cumulative dose of BOTOX® for treatment of blepharospasm in a 30-day period should not exceed 200 Units

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*).

Please see additional Important Safety Information about BOTOX® on following page.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Corneal Exposure and Ulceration in Patients Treated With BOTOX® (onabotulinumtoxinA) for Blepharospasm

Reduced blinking from BOTOX® injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect, and corneal ulceration, especially in patients with VII nerve disorders.

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® are discussed in greater detail in the following sections: *Boxed Warning, Contraindications,* and *Warnings and Precautions*.

Blepharospasm

The most frequently reported adverse reactions following injection of BOTOX® for Blepharospasm include ptosis (21%), superficial punctate keratitis (6%), and eye dryness (6%).

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 aminoglycosides or other agents interfering with neuromuscular transmission (eg, 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 the accompanying full Prescribing Information, including Boxed Warning and Medication Guide.