

Patient name: \_\_\_\_\_

For each muscle, indicate specific injection sites and dose.

Date: \_\_\_\_\_

# XEOMIN® (incobotulinumtoxinA): Patient Muscle Injection Tracker Cervical Dystonia

**Left**

Dosage: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Dosage: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Right**

Dosage: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Possible muscles involved in cervical dystonia

This is intended as an education resource to facilitate a discussion between the physician and patient.  
See accompanying Important Safety Information including BOXED WARNING



## IMPORTANT SAFETY INFORMATION

### INDICATIONS AND USAGE

**XEOMIN®** (incobotulinumtoxinA) is a prescription medicine that is injected into muscles and used to treat adults with:

- upper limb spasticity
- cervical dystonia
- blepharospasm who were previously treated with onabotulinumtoxinA (Botox)®

### IMPORTANT SAFETY INFORMATION

**WARNING: DISTANT SPREAD OF TOXIN EFFECT**  
See full prescribing information for complete **BOXED WARNING**.

**The effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. 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, particularly in those patients who have underlying conditions that would predispose them to these symptoms.**

### CONTRAINDICATIONS

• Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN should be discontinued and appropriate medical therapy immediately instituted. XEOMIN is contraindicated in patients with a known hypersensitivity to the active substance botulinum toxin type A, or to any of the excipients (human albumin, sucrose) in the formulation.

• Use in patients with an infection at the injection site could lead to severe local or disseminated infection. XEOMIN is contraindicated in the presence of infection at the proposed injection site(s).

### WARNINGS AND PRECAUTIONS

• The potency units of XEOMIN are specific to the preparation and assay method used and are not interchangeable with other preparations of botulinum toxin products. Therefore, Units of biological activity of XEOMIN cannot be compared to or converted into Units of any other botulinum toxin products.

• Treatment with XEOMIN 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. When distant effects occur, additional respiratory muscles may be involved. Patients may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. Dysphagia may persist for several months, which may require use of a feeding tube. Aspiration may result from severe dysphagia [See **BOXED WARNING**].

• Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of XEOMIN.

• **Cervical Dystonia:** Treatment with botulinum toxins may weaken neck muscles that serve as accessory muscles of ventilation. This may result in critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these accessory muscles. There have been post-marketing reports of serious breathing difficulties, including respiratory failure, in patients with cervical dystonia treated with botulinum toxin products. Patients with smaller neck muscle mass and patients who require bilateral injections into the sternocleidomastoid muscles are at greater risk of dysphagia. Limiting the dose injected into the sternocleidomastoid muscle may decrease the occurrence of dysphagia.

• **Blepharospasm:** Injection of XEOMIN into the orbicularis oculi muscle may lead to reduced blinking and corneal exposure with possible ulceration or perforation. Lower lid injections should not be repeated if diplopia occurred with previous botulinum toxin injections.

• XEOMIN contains human serum albumin. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and Creutzfeldt-Jakob disease (CJD). No cases of transmission of viral diseases or CJD have ever been reported for albumin.

### ADVERSE REACTIONS

**Upper Limb Spasticity:** The most commonly observed adverse reactions (incidence  $\geq 2\%$  of patients and greater than placebo) for XEOMIN were seizure (3%), nasopharyngitis (2%), dry mouth (2%), and upper respiratory tract infection (2%).

**Cervical Dystonia:** The most commonly observed adverse reactions (incidence  $\geq 5\%$  of patients and greater than placebo) for XEOMIN 120 Units and XEOMIN 240 Units, respectively, were: dysphagia (13%, 18%), injection pain site (9%, 4%), neck pain (7%, 15%), muscle weakness (7%, 11%), and musculoskeletal pain (7%, 4%).

**Blepharospasm:** The most commonly observed adverse reactions (incidence  $\geq 5\%$  of patients and twice greater than placebo) for XEOMIN were eyelid ptosis (19%), dry mouth (16%), dry eye (16%), visual impairment (12%), diarrhea (8%), headache (7%), dyspnea (5%) and nasopharyngitis (5%).

### DRUG INTERACTIONS

Co-administration of XEOMIN and aminoglycoside antibiotics or other agents interfering with neuromuscular transmission, e.g., tubocurarine-type muscle relaxants, should only be performed with caution as these agents may potentiate the effect of the toxin.

Use of anticholinergic drugs after administration of XEOMIN may potentiate systemic anticholinergic effects. The effect of administering different botulinum toxin 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.

### USE IN PREGNANCY

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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