



# Clarifying and communicating CIC<sup>\*</sup> and BOTOX<sup>®</sup>

## Indication Overactive Bladder

BOTOX<sup>®</sup> for injection is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

\*Clean intermittent catheterization.

## IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

### WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX<sup>®</sup> 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 on following pages.

## Compare the BOTOX<sup>®</sup> clinical studies to your own practice

CIC Initiation Requirement in BOTOX <sup>®</sup> Clinical Studies <sup>1</sup>	PVR Threshold	Presence of Symptoms
	≥ 200 mL to < 350 mL	Yes
	≥ 350 mL	Regardless of symptoms

**93.5%**

of patients did NOT initiate CIC in BOTOX<sup>®</sup> clinical studies<sup>1</sup>



**Are your patients saying “no” to BOTOX<sup>®</sup> due to CIC? Give them the facts.  
Look inside for a simple approach to consider when discussing CIC.**

**IMPORTANT SAFETY INFORMATION (continued)**  
**DRUG INTERACTIONS (continued)**

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<sup>®</sup>.

**Please see BOTOX<sup>®</sup> full [Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).**

**Reference: 1.** BOTOX<sup>®</sup> Prescribing Information, October 2019.

## Share these 3 key points with your patients:

### 1 The majority of BOTOX<sup>®</sup> patients do not need to self-catheterize and explain that CIC is temporary, if needed

- “About 94 out of every 100 patients in clinical studies of BOTOX<sup>®</sup> for overactive bladder (OAB) did not need to self-catheterize”<sup>1</sup>
- “If it does happen, it’s usually temporary and we will help you through it”

### 2 Clarify the often misunderstood word “retention”

- “Sometimes it can temporarily become a challenge to empty your bladder. That doesn’t mean you can’t urinate at all, it just means you have difficulty *fully* emptying your bladder”

### 3 A self-catheter is NOT like the kind you see in a hospital

- “It is much smaller, easy to use, and you use it by yourself”
- “Ready to use when it’s needed”
- “It fits in your purse or pocket”

Consider using the new, animated BOTOX<sup>®</sup> patient education video at [botoxoabvideo.com](http://botoxoabvideo.com)

**Put CIC in the right perspective to help achieve BOTOX<sup>®</sup> treatment acceptance.**



\*May not be the actual size. Sizes of catheters may vary.

#### IMPORTANT SAFETY INFORMATION (continued)

##### CONTRAINDICATIONS

BOTOX<sup>®</sup> 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.

BOTOX<sup>®</sup> is contraindicated for intradetrusor injection in patients with a urinary tract infection; or in patients with urinary retention or post-void residual (PVR) urine volume > 200 mL who are not routinely performing clean intermittent self-catheterization (CIC).

##### WARNINGS AND PRECAUTIONS

###### Spread of Toxin Effect

See Boxed Warning.

###### Lack of Interchangeability Between Botulinum Toxin Products

**The potency Units of BOTOX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>. The safety and effectiveness of BOTOX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> (see *Warnings and Precautions*).

###### Dysphagia and Breathing Difficulties

Treatment with BOTOX<sup>®</sup> 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*).

###### Urinary Tract Infections in Patients With Overactive Bladder

BOTOX<sup>®</sup> increases the incidence of urinary tract infection. Clinical trials for overactive bladder excluded patients with more than 2 UTIs in the past 6 months and those taking antibiotics chronically due to recurrent UTIs. Use of BOTOX<sup>®</sup> for the treatment of overactive bladder in such patients and in patients with multiple recurrent UTIs during treatment should only be considered when the benefit is likely to outweigh the potential risk.

#### WARNINGS AND PRECAUTIONS (continued)

##### Urinary Retention in Patients Treated for Bladder Dysfunction

Due to the risk of urinary retention, treat only patients who are willing and able to initiate catheterization post treatment, if required, for urinary retention.

In patients who are not catheterizing, post-void residual (PVR) urine volume should be assessed within 2 weeks post treatment and periodically as medically appropriate up to 12 weeks, particularly in patients with multiple sclerosis or diabetes mellitus. Depending on patient symptoms, institute catheterization if PVR urine volume exceeds 200 mL and continue until PVR falls below 200 mL. Instruct patients to contact their physician if they experience difficulty in voiding as catheterization may be required.

##### Overactive Bladder

In clinical trials, 6.5% of patients (36/552) initiated clean intermittent catheterization for urinary retention following treatment with BOTOX<sup>®</sup> 100 Units as compared to 0.4% of patients (2/542) treated with placebo. The median duration of catheterization for patients treated with BOTOX<sup>®</sup> 100 Units was 63 days (minimum 1 day to maximum 214 days) as compared to a median duration of 11 days (minimum 3 days to maximum 18 days) for patients receiving placebo.

Patients with diabetes mellitus treated with BOTOX<sup>®</sup> were more likely to develop urinary retention than nondiabetics. In clinical trials, 12.3% of patients (10/81) with diabetes developed urinary retention following treatment with BOTOX<sup>®</sup> 100 Units vs 0% of patients (0/69) treated with placebo. In patients without diabetes, 6.3% of patients (33/526) developed urinary retention following treatment with BOTOX<sup>®</sup> 100 Units vs 0.6% of patients (3/516) treated with placebo.

##### 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<sup>®</sup> for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

##### Overactive Bladder

The most frequently reported adverse reactions for overactive bladder occurring within 12 weeks of injection include urinary tract infection (BOTOX<sup>®</sup> 18%, placebo 6%), dysuria (BOTOX<sup>®</sup> 9%, placebo 7%), urinary retention (BOTOX<sup>®</sup> 6%, placebo 0%), bacteriuria (BOTOX<sup>®</sup> 4%, placebo 2%), and residual urine volume (BOTOX<sup>®</sup> 3%, placebo 0%).

A higher incidence of urinary tract infection was observed in patients with diabetes mellitus treated with BOTOX<sup>®</sup> 100 Units and placebo than nondiabetics.

The incidence of UTI increased in patients who experienced a maximum post-void residual (PVR) urine volume ≥ 200 mL following BOTOX<sup>®</sup> injection compared to those with a maximum PVR < 200 mL following BOTOX<sup>®</sup> injection, 44% vs 23%, respectively.

##### Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> may potentiate systemic anticholinergic effects.

**Please see additional Important Safety Information on back.**