

# CALMÉ BLADDER

# **Overactive Bladder (OAB) Treatment Information**

#### Indication

BOTOX<sup>®</sup> is a prescription medicine approved to treat overactive bladder symptoms such as a strong need to urinate with leakage or wetting accidents, urgency, and frequency in adults when another type of medication (anticholinergic) does not work well enough or cannot be taken.

#### **IMPORTANT SAFETY INFORMATION**

BOTOX<sup>®</sup> may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX<sup>®</sup>:

- Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- Spread of toxin effects. The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing

Please see additional Important Safety Information inside and on back cover.



# Education designed for your treatment journey

# Each section can help you move forward in understanding your treatment options

## Coping is not your only option

Discover if your OAB symptoms are really under control or if you've just learned to live with the symptoms.

### **Considering BOTOX®**

Learn about this effective option for people with OAB who may be ready for the next step in treatment when oral medication isn't working or can't be taken because of side effects.

### Your BOTOX® conversation

Get the most out of your conversation about BOTOX<sup>®</sup> with your Urologist or Urogynecologist: ask the right questions and get the answers you need to help make the BOTOX<sup>®</sup> treatment decision that's right for you.

### **Treatment expectations**

Find out what type of results to expect and how re-treatment is needed as few as 2 times a year.

### Coverage, cost, and support

Cost should never be a barrier to BOTOX<sup>®</sup> treatment. Learn how BOTOX<sup>®</sup> is covered by most insurance plans, including Medicare,\* and how commercially insured patients may be eligible for co-payment assistance. You'll also find information about *My Answers. My Support*<sup>®</sup>, the free program that offers helpful tips and information for people who have OAB.

# Keep this brochure and reread the sections you need as you get ready to discuss BOTOX $^{\circ}$ with your doctor.

\*Coverage and out-of-pocket expenses vary.

### IMPORTANT SAFETY INFORMATION (continued)

BOTOX<sup>®</sup> may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX<sup>®</sup>. If this happens, do not drive a car, operate machinery, or do other dangerous activities.



# Recognizing when you may be ready to talk to a doctor

#### IMPORTANT SAFETY INFORMATION (continued)

**Do not take BOTOX® if you:** are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have an infection at the planned injection site.



# Are you just coping with your OAB symptoms?

## Coping with symptoms isn't the same as controlling them

Many with OAB still have symptoms such as leaking, going too often, and the strong and sudden need to go.

## Signs that you're just coping with OAB include:



- Using multiple leakage pads per day
- Planning all your travel around bathroom locations
- Not doing things you like because of the fear of leakage
- Worried about the problem every day

### IMPORTANT SAFETY INFORMATION (continued)

**Do not take BOTOX® for the treatment of urinary incontinence if you:** have a urinary tract infection (UTI) or cannot empty your bladder on your own (and are not routinely catheterizing). Due to the risk of urinary retention (difficulty fully emptying the bladder), only patients who are willing and able to initiate self-catheterization post-treatment, if required, should be considered for treatment.

# Have you already tried OAB medications?

## Did you discover that oral medications:

Didn't work well enough **OR** You couldn't handle the side effects

If this sounds familiar, you are not alone. In 1 study of about 100,000 patients:



According to 2 separate surveys, the top reasons that OAB patients discontinued oral medications were side effects and/or lack of results.

reported that they stopped taking their OAB oral therapy within 6 months.

If you feel like you're just coping with your OAB symptoms, there are other options. Keep reading to learn more.

#### IMPORTANT SAFETY INFORMATION (continued)

**Do not take BOTOX® for the treatment of urinary incontinence if you (continued):** Patients with diabetes mellitus treated with BOTOX® were more likely to develop urinary retention than non-diabetics.



# Describe your symptoms and how you cope with them

Share this with your doctor



## Learning about this option for your next step in treatment

#### **IMPORTANT SAFETY INFORMATION (continued)**

The dose of BOTOX<sup>®</sup> is not the same as, or comparable to, another botulinum toxin product.

Serious and/or immediate allergic reactions have been reported. They include itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX<sup>®</sup> should be discontinued.



# It's time to consider BOTOX®

The American Urological Association (AUA) treatment guidelines recognizes BOTOX<sup>®</sup> as one of the treatment options to consider if:

- You tried self-management (such as pads or drinking less liquids), but it didn't work
- You tried oral medication and either it didn't work or was difficult to tolerate

#### IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all your muscle or nerve conditions such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX<sup>®</sup>.

# Calm your bladder with BOTOX®

BOTOX<sup>®</sup> is different from other treatments. BOTOX<sup>®</sup> is placed in the bladder muscle to target the source of your OAB.



- In your body, certain chemicals travel from nerve cells to muscle cells to make your bladder contract so that you can urinate
- For people who have OAB, these muscles contract uncontrollably, creating leakage, the strong sudden need to go, and going too often

# BOTOX<sup>®</sup> is placed in the bladder muscle, where it helps block the nerve signals that trigger OAB

- Reduces daily leakage episodes by half or more
- Treats the strong need to urinate right away
- Reduces the number of times you need to empty your bladder each day

### ▶ If you want OAB symptom relief, BOTOX<sup>®</sup> can help. Individual results may vary.

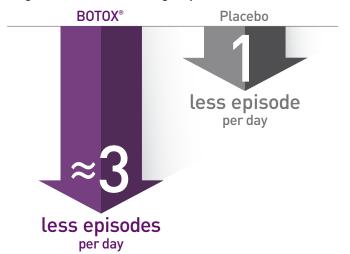
### **IMPORTANT SAFETY INFORMATION (continued)**

Tell your doctor about all your medical conditions, including if you: have or have had bleeding problems; have plans to have surgery; have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence. Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever; have problems emptying your bladder on your own and are being treated for urinary incontinence; are pregnant or plan to become pregnant (it is not known if BOTOX® can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX® passes into breast milk).



# OAB control for people who have already tried oral therapy

In 3 clinical trials, 3 months after treatment, compared to placebo BOTOX<sup>®</sup> was proven to significantly reduce daily leakage episodes



Average decrease in leakage episodes in clinical studies

If oral medication isn't working or you can't take it because of side effects, you may be ready for BOTOX<sup>®</sup>.

#### **IMPORTANT SAFETY INFORMATION (continued)**

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX<sup>®</sup> with certain other medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you have received BOTOX<sup>®</sup> in the past.

# BOTOX<sup>®</sup> reduced daily leakage episodes by half or more

## At week 12 in clinical trials:



The majority of patients receiving BOTOX<sup>®</sup> had **at least 50% reduction** of daily leakage episodes.



Many of these patients **reduced their leakage** episodes by **75%**.



Approximately 1 in 4 patients reported leakage episodes stopped completely.

Reduction of Urinary Incontinence (UI) episodes in 3 clinical trials:

Study 1: BOTOX® n = 280, placebo n = 277; Study 2: BOTOX® n = 277, placebo n = 271; Study 3: BOTOX® n = 145, placebo n = 60

- Patients with ≥ 50% reduction: BOTOX<sup>®</sup> 57.5%, 63.5%, and 77.2%; placebo 28.9%, 33.2%, and 33.3% (P < .001)
- Patients with ≥ 75% reduction: BOTOX<sup>®</sup> 44.6%, 47.3%, and 55.2%; placebo 15.2%, 20.3%, and 21.7% (P < .001)
- Patients with 100% reduction: BOTOX<sup>®</sup> 22.9%, 31.4%, and 33.8%; placebo 6.5%, 10.3%, and 11.7% (P < .001)

### **IMPORTANT SAFETY INFORMATION (continued)**

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*<sup>°</sup>, *Dysport*<sup>°</sup>, or *Xeomin*<sup>°</sup> in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.



# By significantly reducing daily leakage episodes, BOTOX<sup>®</sup> may positively impact your daily life

## Results of a questionnaire:

Patients in BOTOX<sup>®</sup> clinical trials reported improvement in their overall quality of life based on 3 categories<sup>\*</sup>:



# Avoidance and limiting behavior

Such as overplanning every detail of your day in advance, worrying about where bathrooms are, and limiting how much fluid you drink.



# Psychosocial impact

Such as being preoccupied or frustrated with how your condition impacts your everyday decisions, such as what you can wear, where you can go, and how you feel about your overall well-being.



## Social embarrassment

Such as being embarrassed or worried that your symptoms might be noticed by others.

\*These improvements were reported using the Incontinence Quality of Life questionnaire (iQOL). This is a validated questionnaire that is used to measure the impact of urinary incontinence on a patient's quality of life.

### IMPORTANT SAFETY INFORMATION (continued)

Other side effects of BOTOX<sup>®</sup> include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes. In people being treated for urinary incontinence, other side effects include: urinary tract infection, painful urination, and/or inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX<sup>®</sup>, you may need to use a disposable self-catheter to empty your bladder up to a few times each day until your bladder is able to start emptying again.

# YOUR BOTOX® CONVERSATION

## Talking with your doctor about BOTOX<sup>®</sup> and your treatment decision

#### **IMPORTANT SAFETY INFORMATION (continued)**

BOTOX<sup>®</sup> may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX<sup>®</sup>:

- Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- Spread of toxin effects. The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing



# Set goals for your BOTOX<sup>®</sup> conversation

If you feel that you don't yet understand your treatment options, talk to your doctor

# Research has shown that people with OAB think it's important to get information such as:

A treatment recommendation from your doctor

 A better understanding of your treatment options

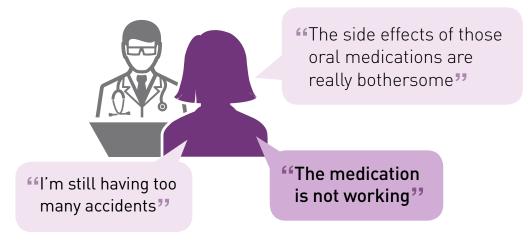
A treatment for your symptoms, but not so many details that you feel overwhelmed

### **IMPORTANT SAFETY INFORMATION (continued)**

BOTOX<sup>®</sup> may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX<sup>®</sup>. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

# Voice your needs

# Tell your doctor how you feel and what you want from treatment



Your treatment journey can continue with a conversation about BOTOX? Help your Urologist or Urogynecologist give you the answers you need by asking questions.

#### IMPORTANT SAFETY INFORMATION (continued)

**Do not take BOTOX**<sup>®</sup> **if you:** are allergic to any of the ingredients in BOTOX<sup>®</sup> (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*<sup>®</sup> (rimabotulinumtoxinB), *Dysport*<sup>®</sup> (abobotulinumtoxinA); have an infection at the planned injection site.



# Ask questions as needed



# **6** topics your doctor may cover

How well BOTOX® may work for your OAB symptoms ASK: <sup>66</sup>What level of relief should I expect?<sup>77</sup>

Your doctor's firsthand experience ASK: "What has it been like for your other patients who've tried BOTOX"?"

A clear recommendation for BOTOX® ASK: <sup>66</sup>Is BOTOX® a good option for me?<sup>33</sup>

The treatment procedure **ASK: \*\***What happens during the procedure?

### Possible side effects

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ASK: <sup>66</sup>What kind of side effects can occur after receiving BOTOX<sup>®</sup>?<sup>77</sup>

The most common side effect, urinary tract infection, was experienced by approximately 18% (vs 6% in placebo) in clinical trials for OAB. Other most common side effects include painful

or difficult urination, and temporary inability to fully empty your bladder. This list does not cover all the possible serious side effects

of BOTOX<sup>®</sup>. Please refer to the Important Safety Information included throughout this brochure and talk with your doctor.

### Re-treatment schedule ASK: <sup>44</sup>How long does BOTOX® last?<sup>77</sup>

## Let your doctor know if you're ready to commit to BOTOX<sup>®</sup> treatment.

If you need more answers, ask. Your BOTOX<sup>®</sup> treatment decision is important.

# **TREATMENT** EXPECTATIONS

## What to expect with BOTOX<sup>®</sup> treatment and re-treatment

#### IMPORTANT SAFETY INFORMATION (continued)

**Do not take BOTOX® for the treatment of urinary incontinence if you:** have a urinary tract infection (UTI) or cannot empty your bladder on your own (and are not routinely catheterizing). Due to the risk of urinary retention (difficulty fully emptying the bladder), only patients who are willing and able to initiate self-catheterization post-treatment, if required, should be considered for treatment. Patients with diabetes mellitus treated with BOTOX® were more likely to develop urinary retention than non-diabetics.

The dose of BOTOX<sup>®</sup> is not the same as, or comparable to, another botulinum toxin product.



# What to expect with treatment



You may see results after just 2 weeks (you'll have a week-2 follow-up visit)



Symptom check around 4 months (by phone or office visit)



BOTOX<sup>®</sup> may last up to 6 months In clinical trials, BOTOX<sup>®</sup> provided up to 6 months of OAB symptom improvement.



Plan BOTOX<sup>®</sup> re-treatment as few as 2 times a year When your first BOTOX<sup>®</sup> treatment begins to wear off, **discuss re-treatment** and **setting up a regular re-treatment schedule** with your doctor. Wait at least 3 months between treatments.

### > Your BOTOX<sup>®</sup> treatment schedule may be discussed with your doctor.

#### IMPORTANT SAFETY INFORMATION (continued)

Serious and/or immediate allergic reactions have been reported. They include itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.



# Resources to help you start and continue with BOTOX<sup>®</sup> treatment

#### IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all your muscle or nerve conditions such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX<sup>®</sup>.



# **BOTOX**<sup>®</sup> is covered by most insurance plans, including Medicare<sup>\*</sup>

### **Medicare**

### out-of-pocket cost

For most people who have supplemental insurance<sup>+</sup>

# Commercial insurance



### out-of-pocket cost

- With the **BOTOX**<sup>®</sup> **Savings Card**, cost should never be a barrier to starting treatment<sup>‡,§</sup>
- The card helps with your out-of-pocket cost for BOTOX® treatment
- Enroll today at **BOTOXSavingsCard.com** or call 1-800-44-BOTOX, Option 4



\*Based on 2016 data.

<sup>†</sup>Average cost for Medicare patients without supplemental insurance is \$171.

<sup>1</sup>Coverage and out-of-pocket costs vary. Average out-of-pocket cost for commercially insured patients is \$190 (before Savings Card refund). Eligibility and Terms and Conditions apply. Visit BOTOXSavingsCard.com for full program details. The card may be used for up to 4 treatments in a 12-month period. The amount you receive on the card will not be higher than your out-of-pocket costs for BOTOX<sup>®</sup> treatment.

<sup>§</sup>Please see Terms and Conditions on back cover.

### **IMPORTANT SAFETY INFORMATION (continued)**

**Tell your doctor about all your medical conditions, including if you:** have or have had bleeding problems; have plans to have surgery; have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence. Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever; have problems emptying your bladder on your own and are being treated for urinary incontinence; are pregnant or plan to become pregnant (it is not known if BOTOX<sup>®</sup> can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX<sup>®</sup> passes into breast milk).

# Join the BOTOX<sup>®</sup> patient support program



Resources for your OAB journey

Designed to support and encourage you by providing tips and information to help you manage your Overactive Bladder symptoms. You will receive important updates about OAB and BOTOX<sup>®</sup>, co-pay savings, and more.









The program is free to join. **Register today at BOTOXforOAB.com** on the Resources page.

#### IMPORTANT SAFETY INFORMATION (continued)

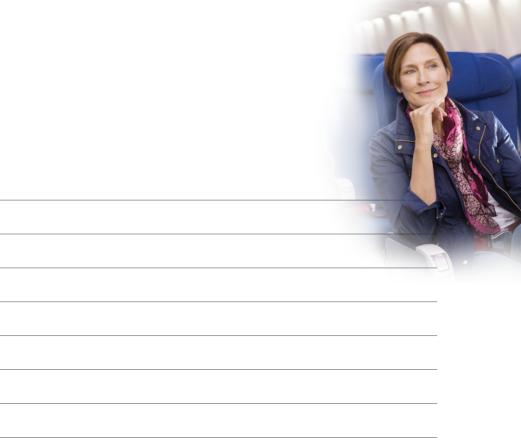
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# Questions for your doctor


#### **IMPORTANT SAFETY INFORMATION (continued)**

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*, *Dysport*, or *Xeomin*, in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.



#### IMPORTANT SAFETY INFORMATION (continued)

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For more information, refer to the <u>Medication Guide</u> or talk with your doctor.



# Join the thousands of others who have taken the next step in treatment



## It may be time to ask your Urologist or Urogynecologist for BOTOX®

 If you don't have a Urologist or Urogynecologist yet, visit BOTOXforOAB.com and click Find a BOTOX<sup>®</sup> Urology Specialist

### Take full advantage of BOTOX<sup>®</sup> support resources. Enroll in My Answers. My Support<sup>®</sup>

#### Where the BOTOX $^{\scriptscriptstyle (\! D\!)}$ Savings Card can be used

The BOTDX® Savings Card can be used for future out-of-pocket costs of BOTDX® treatment, or anywhere Visa® Debit cards are accepted, including supermarkets, pharmacies, clothing stores, and online retailers. The BOTDX® Savings Card is issued by Metropolitan Commercial Bank, member FDIC, pursuant to a license from Visa U.S.A., Inc. "Metropolitan and "Metropolitan Commercial Bank" are registered trademarks of Metropolitan Commercial Bank © 2014. Use of the Card is subject to the terms and conditions of the applicable Cardholder Agreement and fee schedule, if any.

#### Terms and Conditions

By participating, the user understands and agrees to comply with the Program rules as set forth below.

Offer is valid only for BOTOX® and BOTOX® treatment-related costs not covered by insurance. The BOTOX® Savings Card will be funded upon approval of a claim. The claim must be submitted with an Explanation of Benefits (EOB) or a Specialty Pharmacy Provider (SPP) receipt. (If the BOTOX® prescription was filled by a Specialty Pharmacy Provider, both an EOB and SPP receipt must be sent.) All claims must be submitted within 90 days of the date of service listed on the EOB. BOTOX® Savings Card may not be combined with any other offer or discount. This BOTOX® Savings Card is not health insurance.

Offer not valid for patients participating in Medicare, Medicaid, or any similar federal or state healthcare program, including any state medical or pharmaceutical assistance programs. If patients are eligible for drug benefits under such program, they cannot use this BOIOX<sup>85</sup> Savings Card. Offer void where prohibited by law, taxed, or restricted. Offer good only in the United States. Allergan reserves the right to rescind, revoke, and amend this offer without notice.

#### **IMPORTANT SAFETY INFORMATION (continued)**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

#### Please see accompanying Summary of Information about BOTOX®.



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