



Does just one leakage episode feel like one too many?

**BOTOX<sup>®</sup> is just one conversation away**

In BOTOX<sup>®</sup> clinical trials, participants with overactive bladder had to have tried an anticholinergic that didn't work well enough or was difficult to tolerate, and had to have at least 3 leaking or wetting accidents, and were urinating at least 24 times in 3 days.

**If your current Overactive Bladder (OAB) treatment isn't working or you can't tolerate it, ask your doctor if BOTOX<sup>®</sup> can help reduce unwanted leakage interruptions.**

#### **Indication**

BOTOX<sup>®</sup> is a prescription medicine that is injected into the bladder muscle and used to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents, going too often, and the strong, sudden need to go in adults 18 years and older 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, and trouble swallowing

**Please see additional Important Safety Information inside.**

## BOTOX<sup>®</sup> can help

### Learn more about Overactive Bladder (OAB) and BOTOX<sup>®</sup> treatment



#### Take action

Find out how OAB is actually a chronic condition that can be treated. Learn what you can do if your current OAB medication is not working the way you want.



#### Consider BOTOX<sup>®</sup>

When your OAB medication isn't working well enough or is causing unwanted side effects, learn more about how BOTOX<sup>®</sup> can help.



#### Speak up

Make sure you are vocal and let your doctor know how OAB affects your life. Be prepared with the right questions to get the answers you need to determine if BOTOX<sup>®</sup> treatment is right for you.



#### Get ready

Find out what to expect with BOTOX<sup>®</sup> treatment and how re-treatment is as few as 2 times a year.



#### Start saving

Learn how BOTOX<sup>®</sup> is covered by most insurance plans, including Medicare. For patients with commercial insurance, many patients may pay as little as \$0 out of pocket with the BOTOX<sup>®</sup> Savings Program.\*

\*Please see full terms and conditions on page 22.

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

2 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.**

## Take action

If just one leakage episode feels like one too many, tell your doctor how OAB affects you and let them know you want more from your treatment.

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

**Do not receive 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 a skin infection at the planned injection site.

**Please see additional Important Safety Information on following pages.**

## Does this sound like you?

You may still be experiencing leakage despite taking OAB medication and coping by:



Using multiple leakage pads per day

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Planning your travel around bathroom locations

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Not doing things you like because of fear of leakage

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Worrying about your problem every day

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

**Do not receive BOTOX<sup>®</sup> 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.

# How long are you willing to suffer in silence?

OAB is actually a chronic condition that can be treated



Many people think that symptoms of OAB are just part of getting older.



They will often cope with OAB for years before being offered something other than a pill.

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**Make your voice heard and  
tell your doctor how OAB affects you.**

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

**Do not receive BOTOX® for the treatment of urinary incontinence if you: (continued)** In clinical trials, 36 of the 552 patients had to self-catheterize for urinary retention following treatment with BOTOX® compared to 2 of the 542 treated with placebo. Patients with diabetes mellitus treated with BOTOX® were more likely to develop urinary retention than nondiabetics.

**Please see additional Important Safety Information on following pages.**

## You may have already tried OAB medications

Did you discover that your OAB medications:

- Didn't work well enough?     Had side effects you couldn't handle?

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If this sounds familiar, you are not alone.

**In 1 study of about 100,000 patients:**



**71%**

reported that they stopped taking their OAB medication at some point within 6 months.

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**Speak up and tell your doctor if your oral OAB medication isn't working the way you want. There are other options to try.**

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## Consider BOTOX<sup>®</sup>

Tired of taking pills every day that don't work well enough or you can't tolerate?  
Learn how 1 BOTOX<sup>®</sup> treatment about every 6 months can help.

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

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

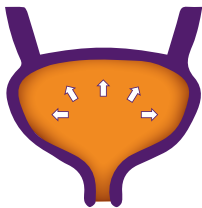
**Serious and/or immediate allergic reactions have been reported** including itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX<sup>®</sup> should be discontinued.

Please see additional Important Safety Information on following pages.

## BOTOX<sup>®</sup> is different from other treatments

### BOTOX<sup>®</sup> is placed locally at 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 directly in the bladder muscle about every 6 months, where it helps block the nerve signals that trigger OAB
- BOTOX<sup>®</sup> does not require surgery or weekly visits to the doctor for treatment



A minimum of 12 weeks is needed between treatments.



#### **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>.

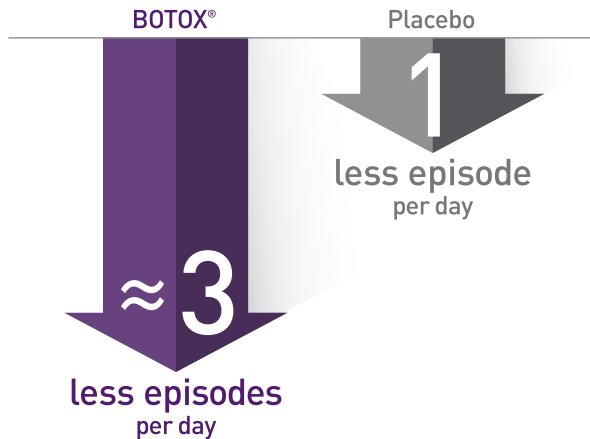


# Proven to work when other OAB medications did not

*In 3 clinical trials, 3 months after treatment, compared to placebo*

## BOTOX® significantly reduced daily leakage episodes

Average decrease in leakage episodes in clinical studies



**If your OAB medication isn't working or you can't take it because of the side effects, you may be ready for BOTOX®**

### **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; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; 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).

Please see additional Important Safety Information on following pages.

# BOTOX<sup>®</sup> reduced 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 **no leakage episodes** after BOTOX<sup>®</sup> treatment



Reduction of urinary incontinence (UI) episodes in 3 clinical trials:

**Study 1:** BOTOX<sup>®</sup> n = 280, placebo n = 277

**Study 2:** BOTOX<sup>®</sup> n = 277, placebo n = 271

**Study 3:** BOTOX<sup>®</sup> n = 145, placebo n = 60

- Patients with  $\geq 50\%$  reduction: BOTOX<sup>®</sup> 57.5%, 63.5%, and 77.2%; placebo 28.9%, 33.2%, and 33.3% ( $P < .001$ )
- Patients with  $\geq 75\%$  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 about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. 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> may positively impact your daily life by significantly reducing daily leakage episodes

*Results of a questionnaire*

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



## 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 (I-QOL). 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)**

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.

Please see additional Important Safety Information on following pages.

## How well is your current OAB medication working?

Can you sit through an entire movie, concert, or dinner without having to get up and use the restroom?

Always |  |  Usually |  |  Never

Do you still need to use pads and diapers?

No |  |  Sometimes |  |  Always

If you're having side effects with your current medication, how much do they bother you?

Not at all |  |  Somewhat bothersome |  |  Really bothers me

What do you hope for from your OAB treatment?

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**Share this with your doctor.**

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

**Other side effects of BOTOX® include:** dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, dry eyes; drooping eyebrows; and upper respiratory tract infection. 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®, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.

## Speak up

Let your doctor know how OAB impacts you and how you feel about your OAB medication. Ask your doctor what more you can do. BOTOX® is just one conversation away.

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

**BOTOX® 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®:**

- **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, and trouble swallowing

**Please see additional Important Safety Information on following pages.**

## Set goals for talking with your doctor

Be prepared so you get the answers you need to help choose the right treatment

### Share with your doctor:

- How OAB symptoms affect you
- How you feel about your current medication
- What you hope to get from OAB treatment

### What you should get from your doctor:

- A better understanding of your treatment options
- What he or she believes is the right option for you



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**A urologist or urogynecologist can help find the treatment that's right for you.**

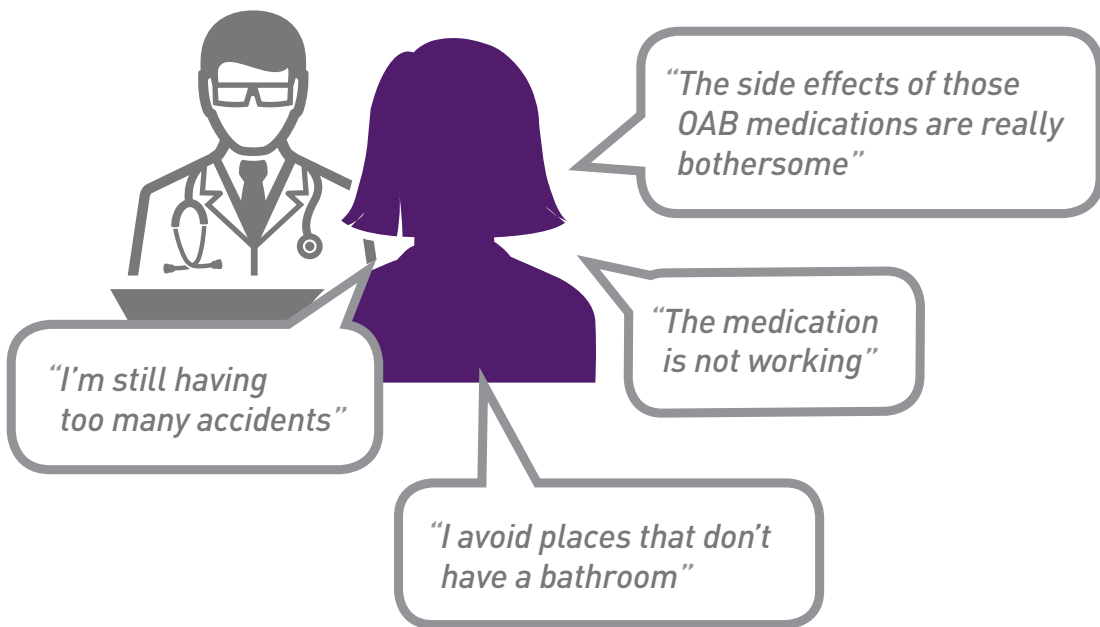
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#### **IMPORTANT SAFETY INFORMATION (continued)**

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 how you feel

Tell your doctor so they understand your perspective



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

**Do not receive 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 a skin infection at the planned injection site.

Please see additional Important Safety Information on following pages.

# Ask questions as needed



## 6 topics you should discuss with your doctor

### 1 How well BOTOX<sup>®</sup> may work for your OAB symptoms

**ASK:** “What results should I expect?”

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### 2 Your doctor’s firsthand experience

**ASK:** “What has it been like for your other patients who’ve tried BOTOX<sup>®</sup>?”

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### 3 A clear recommendation for BOTOX<sup>®</sup>

**ASK:** “Is BOTOX<sup>®</sup> a good option for me?”

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### 4 The treatment procedure

**ASK:** “What happens during the procedure?”

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### 5 Possible side effects

**ASK:** “What kind of side effects can occur after receiving BOTOX<sup>®</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.**

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### 6 Re-treatment schedule

**ASK:** “How often will I need to come in for BOTOX<sup>®</sup> re-treatment? Every 6 months?”





# Get ready

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

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

**Do not receive BOTOX<sup>®</sup> 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.

In clinical trials, 36 of the 552 patients had to self-catheterize for urinary retention following treatment with BOTOX<sup>®</sup> compared to 2 of the 542 treated with placebo. Patients with diabetes mellitus treated with BOTOX<sup>®</sup> were more likely to develop urinary retention than nondiabetics.

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

**Please see additional Important Safety Information on following pages.**

## BOTOX<sup>®</sup> may be given in the comfort and convenience of your doctor's office

The entire process takes about 1 hour

20 minutes to prep

10 minutes to administer BOTOX<sup>®</sup>

30 minutes for evaluation after the procedure



BOTOX<sup>®</sup> is placed in multiple areas of your bladder muscle through a small lighted tube called a *cystoscope*.

- Your bladder will first be numbed with lidocaine for a more comfortable treatment experience

### IMPORTANT SAFETY INFORMATION (continued)

**Serious and/or immediate allergic reactions have been reported** including 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.

# Plan on BOTOX<sup>®</sup> re-treatment about every 6 months

OAB is chronic and requires ongoing treatment



FIRST TREATMENT

Make your 6-month re-treatment appointment **before you leave the office** to stay on schedule.

WEEK 2

You may start to notice results at 2 weeks.

RE-TREATMENT EVERY 6 MONTHS

Talk to your doctor about setting up a **6-month BOTOX<sup>®</sup> re-treatment schedule**.

If your OAB symptoms return before 6 months, contact your doctor so you may be re-treated sooner.

A minimum of 12 weeks is needed between treatments.



Get appointment reminders texted to you.  
Sign up at [BOTOXforOAB.com/support](https://www.BOTOXforOAB.com/support)

## 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>.

Please see additional Important Safety Information on following pages.

## Questions for your doctor

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### **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; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; 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).



## Start saving

Learn about a savings program that may be able to help with BOTOX® out-of-pocket costs.

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

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® 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® in the past.**

Please see additional Important Safety Information on following pages.



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

## Medicare

\$0

out-of-pocket cost

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

## Commercial (private) insurance

You may pay as little as

\$0

out-of-pocket cost

For BOTOX<sup>®</sup> treatment with the BOTOX<sup>®</sup> Savings Program

\*Based on 2016 data. Data are subject to change. Data are not a guarantee of coverage, or partial or full payment, by any payers listed. Actual benefits determined by respective plan administrators. Insurer plans, coverage criteria, and formularies are subject to change without notice. Check coverage with applicable insurer. Allergan does not endorse any individual plans. Formulary coverage does not imply efficacy or safety.

<sup>†</sup>Average cost per treatment for Medicare patients without supplemental insurance is \$86.

### **BOTOX<sup>®</sup> Savings Program Terms and Conditions**

**Program Terms, Conditions, and Eligibility Criteria:** **1.** This offer is good for use only with a valid prescription for BOTOX<sup>®</sup> (onabotulinumtoxinA). **2.** Based on insurance coverage, each patient can be reimbursed up to \$1000 per treatment with a maximum savings limit of \$4000 per year. Patient out-of-pocket expense may vary. **3.** This offer is not valid for use by patients enrolled in Medicare, Medicaid, or other federal or state programs (including any state pharmaceutical assistance programs), or private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs. Patients may not use this offer if they are Medicare-eligible and enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees. This offer is not valid for cash-paying patients. **4.** This offer is valid for up to 4 treatments over a 12-month period. **5.** Offer is valid only for BOTOX<sup>®</sup> and BOTOX<sup>®</sup> treatment-related costs not covered by insurance. **6.** A BOTOX<sup>®</sup> Savings Program check will be provided upon approval of a claim. The claim must be submitted with treatment details from an Explanation of Benefits (EOB) or a Specialty Pharmacy (SP) receipt. (If the BOTOX<sup>®</sup> prescription was filled by a Specialty Pharmacy, both EOB and SP details must be provided.) All claims must be submitted within 120 days of treatment date. You may be required to provide a copy of your EOB or SP receipt for your claim to be approved. **7.** A BOTOX<sup>®</sup> Savings Program check may be sent either directly to you or to your selected healthcare provider who provided treatment. For payment to be made directly to your healthcare provider, you must authorize an assignment of benefit during each claim submission. You are not obligated to assign your BOTOX<sup>®</sup> Savings Program benefit to your healthcare provider to participate in the program. **8.** Allergan reserves the right to rescind, revoke, or amend this offer without notice. **9.** Offer good only in the USA, including Puerto Rico, at participating retail locations. **10.** Void where prohibited by law, taxed, or restricted. **11.** This offer is not health insurance. **12. By participating in the BOTOX<sup>®</sup> Savings Program, you acknowledge that you are an eligible patient and that you understand and agree to comply with the terms and conditions of this offer.**

You may PAY as little as  out of pocket for BOTOX® treatments

How can the BOTOX® Savings Program help you pay as little as \$0 for BOTOX® treatment?\*



Most insurance plans cover the majority of BOTOX® costs, but you may have remaining out-of-pocket costs. Patients with OAB have on average of \$227 per treatment (\$37 per month) in out-of-pocket costs.<sup>†,‡,§</sup> If eligible, the BOTOX® Savings Program may reimburse you to help with these remaining out-of-pocket costs (including costs for both BOTOX® and the procedure).



Visit [BOTOXSavingsProgram.com](https://www.BOTOXSavingsProgram.com) or text SAVE to 27747 to see if you're eligible.<sup>||</sup>

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

<sup>†</sup>Not including those with Medicare/Medicaid or other government programs.

<sup>‡</sup>Covers out-of-pocket costs for BOTOX® for up to \$1000 per treatment, up to \$4000 per year.

<sup>§</sup>Must be commercially insured and meet eligibility criteria to qualify. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Please see terms and conditions.

<sup>||</sup>See Privacy & Terms: [bit.ly/2RwxiWt](https://bit.ly/2RwxiWt). Message & data rates apply. Message frequency may vary. Text HELP for help, STOP to end.

#### **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.

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



Stop compromising.

BOTOX<sup>®</sup> is just one conversation away.

- FDA approved to treat OAB since 2013
- BOTOX<sup>®</sup> cut the number of daily leakage episodes by about half in clinical trials at week 12
- 1 BOTOX<sup>®</sup> treatment can last up to 6 months
- BOTOX<sup>®</sup> is covered by most insurance plans, including Medicare

**Speak up and tell your doctor that you're ready for BOTOX<sup>®</sup>.**  
**Still have questions? Ask your doctor or visit [BOTOXOABVideo.com](http://BOTOXOABVideo.com)**

**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, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, dry eyes; drooping eyebrows; and upper respiratory tract infection. 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 disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.

For more information, refer to the Medication Guide or talk with your doctor.

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

Please see accompanying [Summary of Information](#) about BOTOX<sup>®</sup>.



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## Summary of Information About BOTOX® (onabotulinumtoxinA) for Overactive Bladder

### What is the most important information I should know about BOTOX®?

**BOTOX® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:**

- **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

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

**BOTOX® dosing units are not the same as, or comparable to, any other botulinum toxin product.**

### What is BOTOX®?

BOTOX® is a prescription medicine that is injected into the bladder and used to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents, a strong need to urinate right away, and urinating often in adults 18 years and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken.

### Who should not receive BOTOX®?

Do not receive BOTOX® if you are: allergic to any of the ingredients in BOTOX® such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site; have a urinary tract infection (UTI); or find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing).

### What should I tell my doctor before treatment?

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.

Tell your doctor if you have or have had breathing problems such as asthma or emphysema; swallowing problems; bleeding issues; plan to or have had surgery; have symptoms of a urinary tract infection (UTI). 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.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or plan to breastfeed. It is not known if BOTOX® can harm your unborn baby or if BOTOX® passes into breast milk.

### What are the most common side effects?

The most common side effects include: urinary tract infection, painful urination, bacteria in urine, and the temporary inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX®, you may need to use a small disposable self-catheter to empty your bladder up to a few times each day until your bladder is able to start emptying again.

Other side effects have been reported including allergic reactions (eg, itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint). These are not all of the possible side effects.

Call your doctor for medical advice if you experience any side effects after treatment with BOTOX®.

### What should I tell my doctor about prescription and over-the-counter medicines I take?

Using BOTOX® with certain medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past.** Tell your doctor if you have received an injection with another botulinum toxin product in the last 4 months, such as *Myobloc*®, *Dysport*®, or *Xeomin*®. Be sure your doctor knows which product you received.

Tell your doctor about all prescription, over-the-counter medicines, and supplements you take, including: vitamins and herbal supplements; recent antibiotic injections, anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products or blood thinners. **Ask your doctor if you are not sure whether your medicine is listed above.**

### To learn more

If you would like more information, talk to your doctor and/or go to [BOTOXforOAB.com](http://BOTOXforOAB.com) for full Prescribing Information, including Medication Guide.

You may report side effects to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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