

Frustrated with your Overactive Bladder (OAB) medication not working? Can't handle the side effects?

**BOTOX**<sup>®</sup> treats adults with the OAB symptoms of leaking, going too often, and the strong sudden need to go.



Ask your Urologist or Urogynecologist if **BOTOX**<sup>®</sup> can help calm your bladder.

**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.

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.

Please see additional Important Safety Information inside. Please see accompanying Summary of Information about BOTOX<sup>®</sup>.



### Have you tried Overactive Bladder (OAB) medications and discovered that:

They didn't work well enough? Or

You couldn't handle the side effects?

If this sounds familiar, you are not alone. In one study of 1117 patients,

73.5%

reported that they stopped taking their OAB therapy within 1 year. According to 2 separate surveys, the top reasons that OAB patients discontinued anticholinergics were due to side effects and/or lack of results.

### Do you know all of your options?

The American Urological Association (AUA) treatment quidelines list BOTOX<sup>®</sup> as an appropriate therapy to consider discussing with your doctor when:



Self-management is not effective.

Anticholinergic measure enough or are too difficult to tolerate. Anticholinergic medications do not work well

### Ask your doctor today if BOTOX® is the right option for you.

Please see additional Important Safety Information on the following pages.

### Important Safety Information (continued)

Do not take BOTOX® 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® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*<sup>®</sup> (incobotulinumtoxinA); have an infection at the planned injection site.





BOTOX<sup>®</sup> is a different type of treatment option to consider when another type of medication (anticholinergic) does not work well enough or cannot be taken.

- BOTOX<sup>®</sup> is injected into the bladder muscle:
  - targeting the source of your Overactive Bladder.
  - beginning to reduce daily leakage episodes after just 2 weeks.
- One BOTOX<sup>®</sup> treatment for OAB can last up to 6 months. Talk to your doctor about your re-treatment timing, waiting at least 3 months between treatments.
- In clinical trials, at week 12, adults using BOTOX<sup>®</sup> reduced their average number of daily leakage episodes by about half.

### Ask your Urologist or Urogynecologist if BOTOX<sup>®</sup> can help Calm Your Bladder to significantly reduce your daily leakage episodes.

### 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).



### Important Safety Information (continued)

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<sup>®</sup> were more likely to develop urinary retention than non-diabetics.

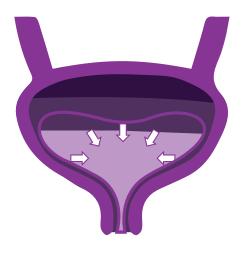
Please see additional Important Safety Information on the following pages.

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# HOW B BOTOX® WORK?

**BOTOX®** treatment works by calming the nerves that trigger the overactive bladder muscle.



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

### BOTOX<sup>®</sup> is injected into the bladder muscle and works on the nerves to help block the signals that trigger OAB, which helps:

- Reduce daily leakage episodes.
- Treat the strong need to urinate right away.
- Reduce the number of times that you need to empty your bladder daily.



### 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.





### When can I expect to see results?



BOTOX<sup>®</sup> is injected into the bladder muscle and begins to work at the source of your Overactive Bladder to reduce daily leakage episodes after just 2 weeks.

### How long does BOTOX<sup>®</sup> last?



BOTOX<sup>®</sup> is not a daily treatment. In clinical trials, one BOTOX<sup>®</sup> treatment provided up to 6 months of OAB symptom improvement. (Your results may vary.)

Talk to your doctor about your re-treatment timing, waiting at least 3 months between treatments.



### Important Safety Information (continued)

as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX®.

Please see additional Important Safety Information on the following pages.

### Important Safety Information (continued)

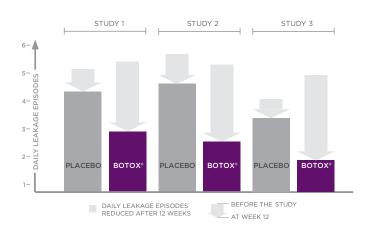
**Tell your doctor about all your muscle or nerve conditions** such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome,



## **PROVEN RESULTS**

In **3** Clinical Trials, 💰 **3** months after treatment

# Patients receiving BOTOX<sup>®</sup> reported a significant reduction in the number of their daily leakage episodes.



### 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;

### At week 12, many of these patients saw their daily leakage episodes reduced by half or more following BOTOX® treatment.\*



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



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



**Approximately 1 in 4** of them reported they were experiencing no leakage episodes.

In clinical trials, one BOTOX<sup>®</sup> treatment provided symptom improvement for up to 6 months. Your doctor will work with you to develop a re-treatment plan.

\*Reduction of Urinary Incontinence (UI) episodes in pivotal studies:

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

- Patients with ≥50% reduction: BOTOX<sup>®</sup> 57.5%, placebo 28.9% (*P* <.001)
- Patients with ≥75% reduction: BOTOX<sup>®</sup> 44.6%, placebo 15.2% (P <.001)
- Patients with 100% reduction: BOTOX<sup>®</sup> 22.9%, placebo 6.5% (*P* <.001)

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

- Patients with ≥50% reduction: BOTOX<sup>®</sup> 63.5%, placebo 33.2% (*P* <.001)
- Patients with >75% reduction: BOTOX® 47.3%, placebo 20.3% (*P* <.001)
- Patients with 100% reduction BOTOX<sup>®</sup> 31.4%, placebo 10.3% (*P* <.001)

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

- Patients with ≥50% reduction: BOTOX<sup>®</sup> 77.2%, placebo 33.3% (P <.001)
- Patients with ≥75% reduction: BOTOX<sup>®</sup> 55.2%, placebo 21.7% (*P* <.001)
- Patients with 100% reduction BOTOX<sup>®</sup> 33.8%, placebo 11.7% (*P* <.001)

### Important Safety Information (continued)

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).



## RESULTS IN ACTION

By significantly reducing daily leakage episodes, BOTOX<sup>®</sup> treatment may make a positive impact on your daily life.

Based on results of a questionnaire\* completed by patients in the BOTOX® clinical trials, patients on BOTOX® reported improvement in their overall quality of life. This questionnaire asked patients to consider three specific categories that are commonly important to people living with Overactive Bladder:



### Avoidance and Limiting Behavior

Such as overplanning every detail of your day in advance. Including worrying about where bathrooms are and/or 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)

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.

## **BEFORE, DURING & AFTER**

## BOTOX<sup>®</sup> treatment can be given in the convenience of a doctor's office.

Once you and your doctor decide that BOTOX<sup>®</sup> is right for you, very often it can be administered in your Urologist's or Urogynecologist's office.

### Before your treatment day:

• Your doctor will prescribe an antibiotic to prevent against a urinary tract infection.

### On the treatment day:



- Your doctor will numb your bladder for a more comfortable treatment.
- Once your bladder is numb, a small lighted tube called a cystoscope will be inserted through the urethra (the natural opening where the urine comes out).



 BOTOX<sup>®</sup> is injected through the cystoscope into multiple areas of your bladder muscle.



• The entire process takes approximately one hour: 30 minutes to prepare and administer the BOTOX® and 30 minutes for post-procedure evaluation.

You should not experience significant pain after the BOTOX® treatment, although it may sting or burn when you urinate the first few times. You may also see some blood in the urine right after treatment, but significant bleeding is rare. See your doctor if either of these symptoms persists.

Please read about common side effects on p. 14 and discuss any questions you may have with your doctor.



## TREATMENT CONSIDERATIONS

### You should not receive BOTOX<sup>®</sup> if you:

- Have a current urinary tract infection (UTI).
- Are not willing (or able) to use a disposable self-catheter if necessary.

### Side effects

It's always important to consider the potential side effects of any medication and equally weigh the benefits and risks with your doctor before making a decision.

The most common side effects after a BOTOX<sup>®</sup> treatment were:

- Urinary tract infection (18% vs 6% with placebo)
- Painful or difficult urination (9% vs 7% placebo)
- Inability to fully empty your bladder, which may require the temporary use of a self-catheter (6% vs 0% placebo)
- Few patients discontinued the BOTOX<sup>®</sup> for OAB clinical studies because of side effects (1.5% of patients taking BOTOX<sup>®</sup> compared to 0.9% of patients taking placebo).
- This is not a complete list of side effects. Please see the Important Safety Information throughout this brochure, and if you have any questions, talk to 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



### Important Safety Information (continued)

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.

# INSURANCE

### Most insurances (including Medicare and Medicaid) provide coverage for BOTOX<sup>®</sup> for OAB.\*

### For Medicare Patients

Patients with Medicare and supplemental insurance have no out-of-pocket cost.<sup>+</sup>

### For Patients With Commercial Insurance

Allergan offers a BOTOX<sup>®</sup> Savings Card to help with out-of-pocket costs.

With this program, most commercially insured patients are able to have their BOTOX<sup>®</sup> treatment for little to no out-of-pocket cost.

- This program is for patients currently receiving or new to BOTOX® treatment for Overactive Bladder.
- Restrictions apply. Please see full Eligibility Rules for more details at BOTOXSavingsCard.com.

\*Based on Jan.-Dec. 2014 data.

<sup>+</sup>Average cost for Medicare patients with no supplemental insurance is \$173.32.

### Important Safety Information (continued)

**Other side effects of BOTOX® 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.





# ENROLL TODAY

If you have commercial insurance, find out if you are eligible for savings on your out-of-pocket costs. Online - BOTOXSavingsCard.com Call - 1-800-44-BOTOX, option 4

The BOTOX<sup>®</sup> Savings Card is issued by Metropolitan Commercial Bank, member FDIC, pursuant to license by Visa USA, Inc. "Metropolitan Commercial Bank" and "Metropolitan" are registered trademarks of Metropolitan Commercial Bank © 2014. See the Cardholder Agreement for Terms and Conditions. By accepting, signing, or using this savings card, you agree to the Terms and Conditions of the Cardholder Agreement. This savings card will remain the property of the issuing institution and the privilege of its use may be withdrawn at any time.

### Important Safety Information (continued)

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.



## Start a productive conversation with your doctor today.

Share your answers to the following questions:

- **Y N** Do you live with the Overactive Bladder (OAB) symptoms of leakage, going too often, or the strong sudden need to go?
  - Y Do you feel your current OAB medication is not working well enough?
  - Y N Are you having difficulty tolerating the side effects of your current OAB medication?

Hear from others like you. Go to BOTOXforOAB.com and listen to patients discuss their experience with BOTOX<sup>®</sup>.

# ENGAGE S DOCTOR

My OAE	3 Medica	tion His	tory		
Additio	nal Ques	tions			

### Important Safety Information (continued)

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

### 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.



my answers my support

### Resources for your OAB journey

Living with OAB can be challenging. But the good news is you're not alone. The *My Answers. My Support*® Program has been designed to provide helpful information about BOTOX® treatment, including patient testimonials, valuable offers, and ongoing support.







Helpful reminders

Lifestyle tips

**Co-pay savings** 

The program is free to join. So take the first step and register today at BOTOXforOAB.com.

### 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.



### 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 selfcatheterization 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.







### TREATMENT CAN LAST UP TO 6 MONTHS

- Results may vary; talk to your doctor about your re-treatment timing.
- You must wait 3 months between treatments.

### WEEKS TO EXPERIENCE RESULTS

 In clinical trials, patients taking BOTOX<sup>®</sup> experienced fewer leakage episodes in as little as 2 weeks.



### TIMES FEWER ACCIDENTS

 In clinical trials, at week 12, patients who received BOTOX<sup>®</sup> had nearly 3 times fewer accidents than those who did not.

### Talk to a BOTOX<sup>®</sup> Urology Specialist. Find one today at BOTOXforOAB.com

### 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.

### Please see additional Important Safety Information and Summary of Information about BOTOX<sup>®</sup> inside.

🔹 Allergan

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Dysport is a registered trademark of Ipsen Biopharm Limited. Myobloc is a registered trademark of Solstice Neurosciences, Inc. Xeomin is a registered trademark of Merz Pharma GmbH & Co. KGaA. VISA is a registered trademark of Visa International Service Association.

Reference: Data on file, Allergan Inc.

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

## What is the Most Important Information I should know about BOTOX®?

BOTOX<sup>®</sup> 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<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.

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<sup>®</sup> dosing units are not the same as, or comparable to, any other botulinum toxin product.

### What is BOTOX®?

BOTOX<sup>®</sup> is prescription medicine that is injected into the bladder and used to treat adults with overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency), when another type of medicine (anticholinergic) does not work well enough or cannot be taken.

### Who Should Not Take BOTOX®?

Do not use BOTOX<sup>®</sup> if you are: allergic to any of the ingredients in BOTOX<sup>®</sup> such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as *Myobloc*<sup>®</sup> (rimabotulinumtoxinB), *Dysport*<sup>®</sup> (abobotulinumtoxinA), or *Xeomin*<sup>®</sup> (incobotulinumtoxinA); 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 amyotrophic lateral sclerosis (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<sup>®</sup> can harm your unborn baby or if BOTOX<sup>®</sup> passes into breast milk.

### What Are The Most Common Side Effects?

The most common side effects include: urinary tract infection, painful urination, 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 e.g. 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<sup>®</sup>.

### What Should I Tell My Doctor About Prescription and Non-prescription Medicines I Take?

Using BOTOX<sup>®</sup> 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<sup>®</sup> 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*<sup>®</sup>, *Dysport*<sup>®</sup>, or *Xeomin*<sup>®</sup>. 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 products; 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 for full Prescribing Information, including Medication Guide.

You may report side effects to the FDA at www.fda.gov/ medwatch or call 1-800-FDA-1088.

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