



A Guide to Urinary Incontinence (UI) in Adults With Overactive Bladder (OAB) Due to a Neurologic Condition

Information and treatment options

BOTOX® is a prescription medicine that is injected into muscles and used to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication.

IMPORTANT SAFETY INFORMATION

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 (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Please see additional important safety information inside/throughout this brochure.

If you're living with a neurologic condition that causes overactive bladder (OAB) leading to urinary incontinence (UI)—involuntary leakage of urine¹—this booklet was written for you.

Maybe your medication doesn't seem to be working for you, or you cannot tolerate the side effects. We understand that you may be frustrated and wondering what to do next.

One important step you can take is to become an active partner with your physician.

After all, it's your life and your health. Knowledge can help you take more control. And when you ask questions, you can find out more about treatment options that you and your doctor determined may be right for you—from making simple changes in behavior to medication and surgery.

Ask your physician:

- What are my treatment options?
- What should I think about when considering my treatment options?
- What sort of results am I likely to see?
- What risks are involved?

As you read, you'll understand more about the importance of these questions. Most likely, you'll think of many more of your own. You're on your way to getting the help you need.

Important Safety Information (cont.)

Do not take BOTOX® (onabotulinumtoxinA) 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.

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.

Please see additional Important Safety Information on the following page.



Learn all you can

When you learn more about *how* the bladder normally works and *why* neurologic conditions can cause OAB and UI, you gain a deeper understanding of *what* you and your physician can do together.

In the pages that follow, we'll look at:

- How the bladder works
- How the brain and bladder communicate
- How a neurologic condition can cause OAB and UI
- How your doctor assesses OAB due to a neurologic condition
- What your treatment options are

Let's start with the bladder and brain-bladder communication.

Important Safety Information (cont.)

The dose of BOTOX® (onabotulinumtoxinA) is not the same as, or comparable to, another botulinum toxin product.

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

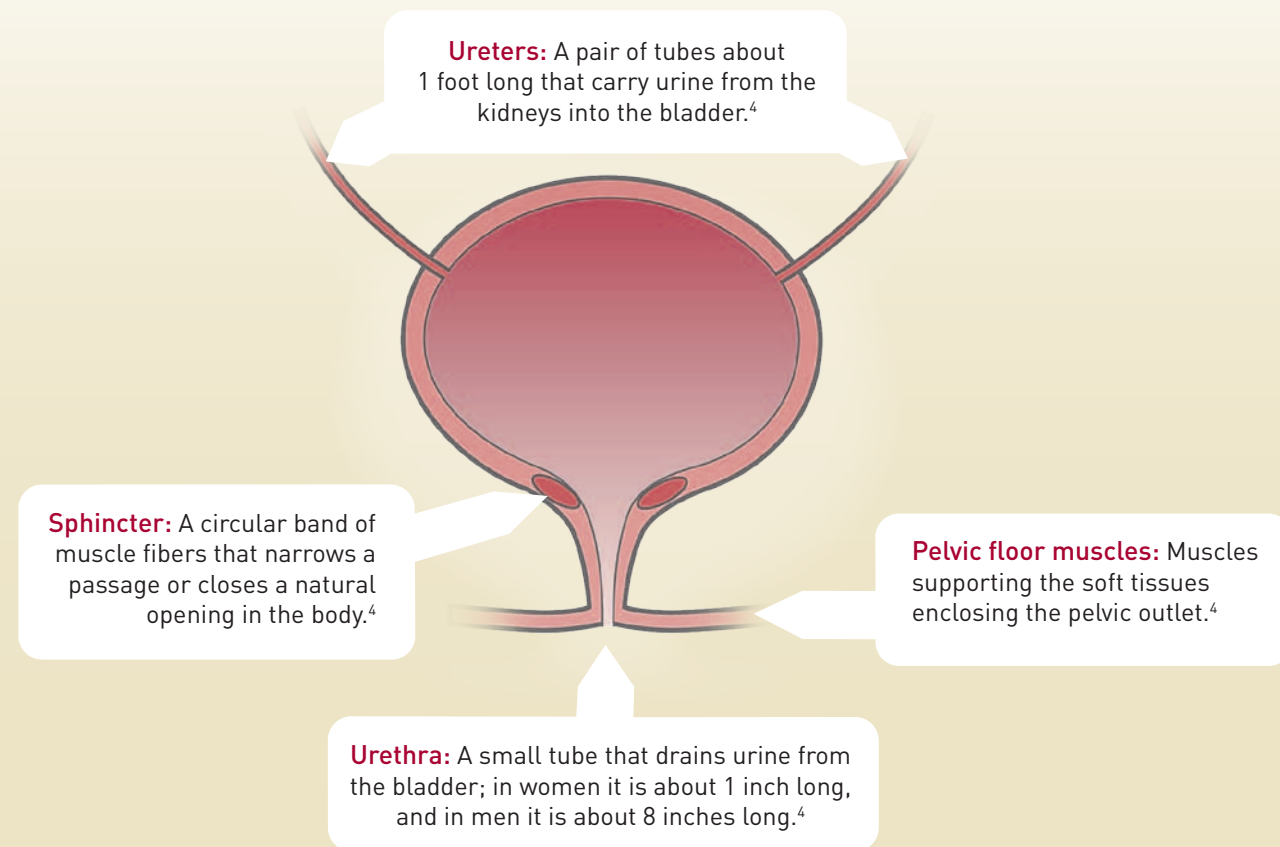
Please see additional Important Safety Information on the following page.

How does the bladder work?

The bladder works in 2 separate stages: storage and emptying.^{2,3}

During storage, the bladder muscle is relaxed to allow the bladder to fill with urine. Ring-shaped *sphincter* muscles contract in the *urethra* (the tube carrying urine from the bladder to the outside of your body) to help prevent involuntary emptying of urine.³

During the emptying stage, the bladder muscle contracts (tightens), causing an increase in pressure inside the bladder. At the same time, the sphincter muscles in the urethra relax, and urine flows out.³



Important Safety Information (cont.)

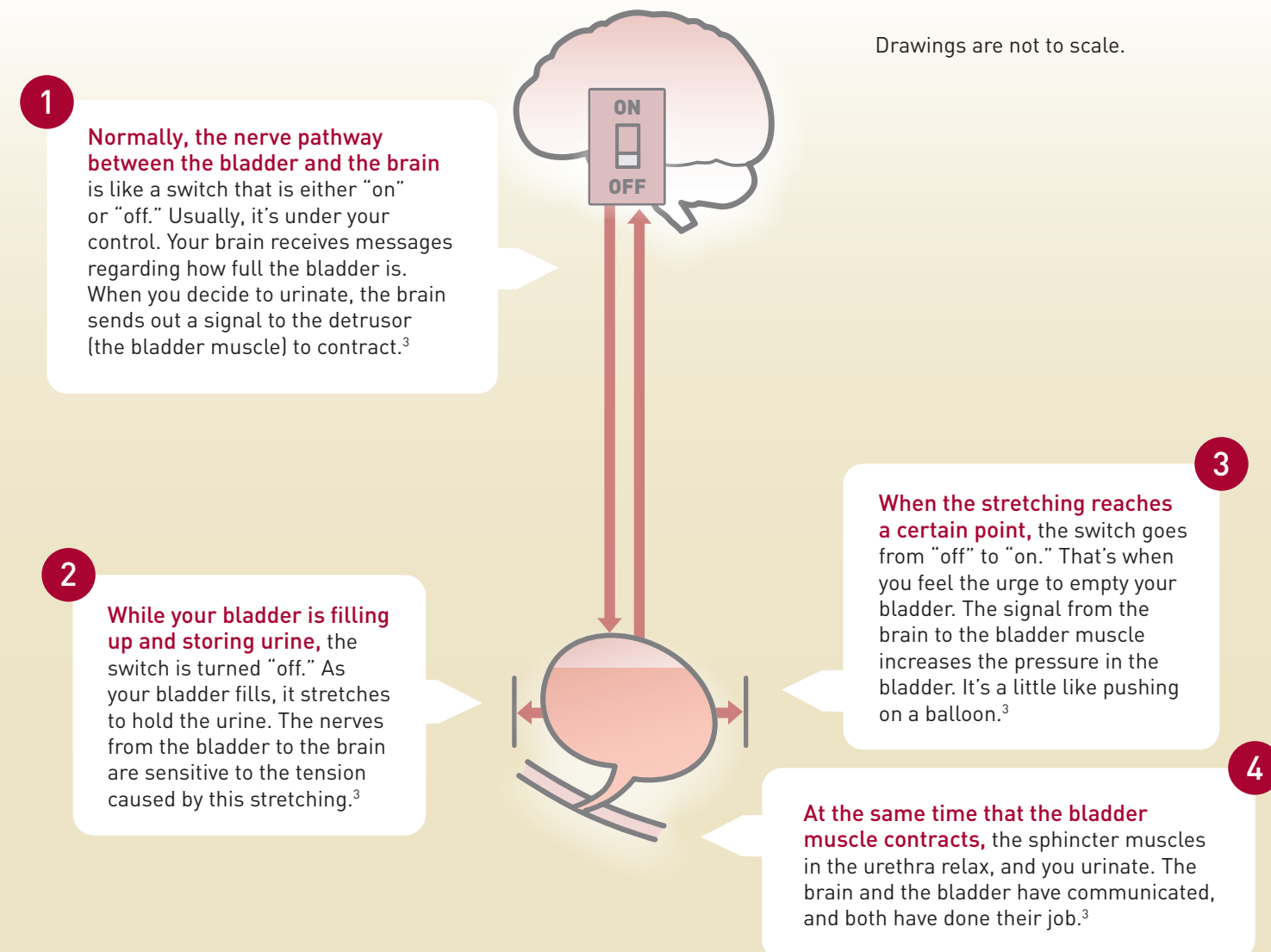
Tell your doctor about all your muscle or nerve conditions such as amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including severe dysphagia (difficulty swallowing) and respiratory compromise (difficulty breathing) from typical doses of BOTOX® (onabotulinumtoxinA).

Tell your doctor if you have any breathing-related problems. Your doctor will want to monitor you for any breathing problems during your treatment with BOTOX® for detrusor overactivity associated with a neurologic condition.

Please see additional Important Safety Information on the following page.

How do the brain and bladder communicate?

Control of urination is partly involuntary. You don't feel your bladder store urine until it reaches a certain point. Then nerves send a message to your brain, which creates an urge to empty the bladder.³ Urination is also partly voluntary. Usually, people have the ability to empty the bladder at a socially appropriate time and place. However, the process described below can be disrupted by injuries to the spinal cord or brain.³



Important Safety Information (cont.)

Human albumin and spread of viral diseases

BOTOX® (onabotulinumtoxinA) contains albumin, a protein component of human blood. The potential risk of spreading viral diseases (eg, Creutzfeldt-Jakob disease [CJD]) via human serum albumin is extremely rare. No cases of viral diseases or CJD have ever been reported in association with human serum albumin.

Please see additional Important Safety Information on the following page.

How can a neurologic condition cause urinary incontinence?

The illustration on the previous page shows how the brain and bladder communicate through nerves so that a person is able to control urination.

In people living with a neurologic condition, such as multiple sclerosis or spinal cord injury, some of these nerves may no longer work the way they should, so the bladder is not able to communicate properly with the brain.¹⁻³

When brain-bladder communication is disturbed or lost, it can lead to various problems.^{1,2} During the storage stage, the bladder muscle may contract involuntarily, even when the bladder is not full (in other words, the bladder muscle is overactive). As a result, a person with a neurologic condition may experience leakage or urine or wetting.²



Important Safety Information (cont.)

Tell your doctor about all your medical conditions, including if you have: plans to have surgery; had surgery on your face; weakness of forehead muscles, such as 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® [onabotulinumtoxinA] can harm your unborn baby); are breastfeeding or plan to breastfeed (it is not known if BOTOX® passes into breast milk).

Please see additional Important Safety Information on the following page.

How does your urologist assess UI due to a neurologic condition?

UI due to a neurologic condition should be further assessed by special tests, which are performed in a urologist's office. These tests are called *urodynamics*, or *urodynamic assessments*.^{2,5,6}

Your urologist can use these tests to measure the following^{2,5}:

- Bladder pressure—the pressure inside the bladder
- Bladder capacity—how much urine your bladder can hold
- Bladder muscle pressure—how much pressure the bladder muscle causes when it contracts

For people living with neurologic conditions, it's important to get regular assessments from your urologist.

The special tests described above can help provide insight into the appropriate treatment for you and help your urologist understand how well your treatment is working.^{2,6}



Important Safety Information (cont.)

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. 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 the following page.

Treatment considerations: What are your options?

If you have UI due to a neurologic condition, various treatment options may help^{2,6}:

- Reduce the pressure inside the bladder
- Increase the amount of urine your bladder can hold (bladder capacity)
- Reduce urinary incontinence

Behavioral therapy

This type of therapy helps you to change some of your behavior to reduce urinary incontinence. It can include the following^{5,7}:

- Bladder diary—a tool that helps you keep track of your bladder’s “behavior” over time
- Timed voiding—you empty your bladder at set intervals, whether you feel you have to or not; this may help decrease urgency and urinary incontinence
- Change in diet—incontinence can be made worse by spicy foods or by drinks containing caffeine (such as coffee or soda) or acid (such as orange juice); these can irritate the bladder
- Watching how much fluid you drink—too much fluid can lead to incontinence, but sometimes too little fluid can cause dehydration and can cause incontinence too, because more concentrated urine can irritate the bladder

Medication

Many people with urinary incontinence take *anticholinergic* medicine (sometimes also called *antimuscarinics*).^{1,6,7}

There are many FDA-approved anticholinergics that treat overactive bladder (OAB) with symptoms of urinary incontinence, urgency, and frequency. Anticholinergics can help people suffering from OAB achieve meaningful improvements in their symptoms.⁷

Anticholinergics help to prevent a particular chemical messenger (*acetylcholine*) from signaling to the bladder muscle.^{2,8} That can help prevent involuntary bladder contractions, increase bladder capacity, and reduce nerve signals from the bladder (for example, feeling full or irritated).^{2,7}

Talk with your doctor about the medication and the dose that may be right for you.

Clean intermittent catheterization (CIC)

In some people with UI due to a neurologic condition, the bladder may not empty as completely as it should.² To help empty this urine, a *catheter* (a small, thin tube) is inserted through the urethra into the bladder. This is called catheterization. This can be self-administered or done by a caregiver. *Intermittent* means that the catheter is not left in, but is used when needed. *Clean* means that each time catheterization is done, the catheter has been washed and dried, or a new catheter is used.⁵

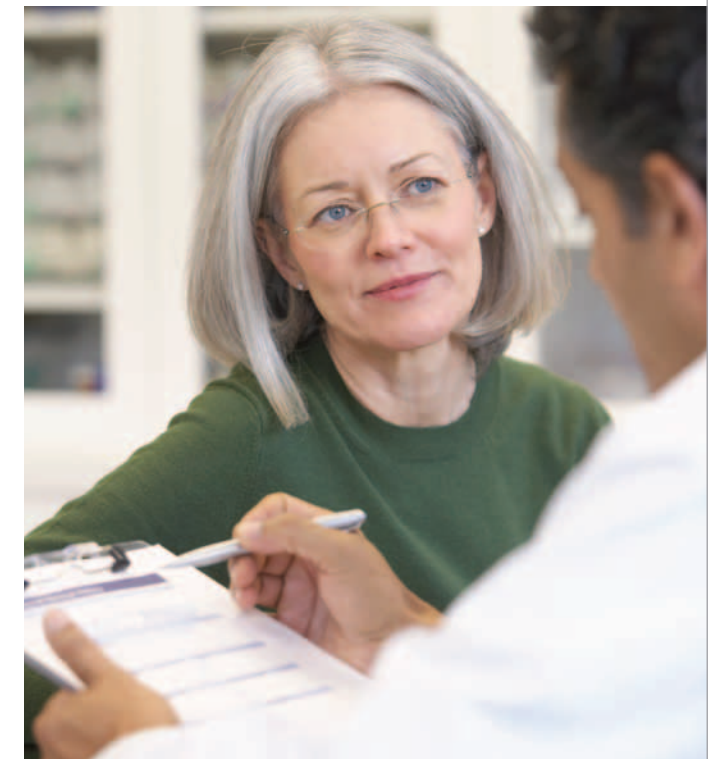
Nerve stimulation (neuromodulation)

In the nervous system, some nerves excite or activate muscles. Other nerves work more like a brake and restrain or slow down muscle action, or even the action of other nerves.⁸

Some FDA-approved devices are designed to attempt to restore the balance between activation and slowing down in the nervous system by stimulating nerves within the bladder, in the pelvic area, or near the lower back. This is called *neuromodulation*.⁷

Surgery

One of the most common surgeries to treat OAB due to a neurologic condition is called *bladder augmentation*. The surgeon removes a piece of the intestine and uses it to increase the size of the bladder.⁸ This surgery can help increase bladder capacity and reduce bladder pressure. Patients who have this surgery may require clean intermittent catheterization (CIC).^{6,8,9}



Talk to your physician about the variety of treatment options available to you.

If you’ve tried an anticholinergic for your UI and still have leakage or cannot tolerate the side effects, your physician may recommend BOTOX® (onabotulinumtoxinA). See the next page for more information.

Important Safety Information (cont.)

Especially 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 (be sure your doctor knows 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 anti-platelets (aspirin-like products) or anti-coagulants (blood thinners).

Please see additional Important Safety Information on the following page.

Important Safety Information (cont.)

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; urinary tract infection and/or inability to empty your bladder on your own (in people being treated for urinary incontinence).

Please see additional Important Safety Information on the following page.

Another treatment option for adults with UI due to neurologic disease

If you've tried an anticholinergic without success, ask your urologist about BOTOX® (onabotulinumtoxinA).

BOTOX® is approved to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication.¹⁰

BOTOX® helps prevent the chemical messenger acetylcholine from signaling the bladder muscle. This reduces the activity of the bladder muscle and helps increase bladder capacity, decrease bladder pressure, and reduce the number of leakage episodes. Another way that BOTOX® is believed to work is by reducing sensory signals coming from the bladder.¹⁰

What should you expect with BOTOX® treatment?

BOTOX® treatment can be done in your urologist's office. Your urologist will administer BOTOX® in the bladder wall.¹⁰

In clinical trials, 6 weeks after treatment¹⁰:

- BOTOX® patients had about 20 fewer leakage episodes on average each week (compared to about 11 fewer for placebo patients)
- The amount the bladder can hold increased for BOTOX® patients compared to placebo
- Pressure caused by the bladder muscle was reduced for BOTOX® patients compared to placebo

Treatment with BOTOX® lasted up to 42 - 48 weeks.¹⁰

Important Safety Information (cont.)

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 a skin infection at the planned injection site.

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.

Please see additional Important Safety Information on the following page.

You should know the most common side effects as well as the benefits. In studies, 31% of patients not already using a catheter had to begin using a catheter within the treatment cycle (compared to 7% of patients receiving placebo).¹⁰

Urinary tract infections (UTIs) occurred in 24% of people receiving BOTOX® compared to 17% receiving placebo.¹⁰

Other common side effects reported in the clinical trials were urinary retention (17% for BOTOX® compared to 3% for placebo), blood in the urine (4% for BOTOX® compared to 3% for placebo), fatigue (4% for BOTOX® compared to 1% for placebo), and insomnia (2% for BOTOX® compared to 0% for placebo).¹⁰

This is not a complete list of side effects. For a complete list, see the Medication Guide provided by your doctor. In addition, see the Important Safety Information throughout this brochure. Please talk with your physician about any additional concerns you may have.

UI due to a neurologic condition is not something you have to live with.

It's important for you to talk to your physician about what you can do.

The sooner you ask your physician or urologist about special tests for UI due to a neurologic condition, the sooner you can receive treatment appropriate for you.

Glossary

Anticholinergics (also known as antimuscarinics)

FDA-approved medications that treat overactive bladder (OAB) with symptoms of urinary incontinence, urgency, and frequency.^{1,6,7}

Bladder capacity

How much urine your bladder can hold. This can be measured using urodynamics (special tests done in your urologist's office).⁵

Bladder muscle pressure

How much pressure the bladder muscle causes when it contracts.^{2,5}

Bladder pressure

The pressure inside your bladder. This can be measured using urodynamics (special tests done in your urologist's office).⁵

Catheterization

Inserting a small, thin tube (catheter) through the urethra into the bladder to help the bladder empty completely. Some catheters are permanent; others are removed and placed back in when needed (intermittent).^{5,8}

Clean intermittent catheterization (CIC)

Washing and drying a catheter for each use or using a new catheter for intermittent catheterization (removing and replacing catheters).^{5,8}

Placebo

An inactive substance such as a sugar pill or saline (salt water).⁴ A placebo helps researchers show a difference between the effect of a study medication and no treatment. The placebo in the BOTOX® clinical studies was a saline (salt water) injection.¹⁰

Timed voiding

Emptying the bladder at set times, even when a person doesn't feel the need to; a technique to help decrease urgency and urinary incontinence.⁷

Ureters

Tubes that carry urine from the kidneys to the bladder.⁴

Urethra

Small tube that drains urine from the bladder. In women it is about one inch long, and in men it is about 8 inches long.⁴

Urinary frequency

Urinating more often than normal and before the bladder is full.⁴

Urinary incontinence (UI)

Leakage of urine that is not under a person's voluntary control.^{4,5}

Urinary incontinence (UI) due to a neurologic condition

When the bladder muscle contracts too often in people living with a neurologic condition. The bladder may not be able to communicate properly with the brain.¹⁻³ When the bladder is filling, the bladder muscle should be relaxed, but overactive bladder due to a neurologic condition causes it to contract involuntarily. This can lead to involuntary leakage of urine, or urinary incontinence.²

Urinary retention

When the bladder cannot empty completely, even after urination.⁴

Urinary tract infection (UTI)

Infection of one or more structures in the urinary system that can cause urinary frequency, burning pain with urination, and possibly blood and/or pus in urine.⁴

Urinary urgency

The sudden, nearly uncontrollable feeling that you have to urinate.⁴

Urodynamics

Special tests done by your urologist to measure things like bladder pressure, bladder capacity, and detrusor pressure. These tests can assess whether a person has overactive bladder due to a neurologic condition.^{2,5,6}

Urologist

A physician who specializes in the urinary system and its disorders.⁴

You and your physician can do something about urinary incontinence due to a neurologic condition.

If you are living with overactive bladder due to a neurologic condition, this booklet was written to give you information about bladder function and possible treatment options.

Please talk with your physician about all of the treatment options available to you. You can visit BOTOXforIncontinence.com to learn more or locate a urologist in your area.

Important Safety Information (cont.)

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

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

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 or call 1-800-FDA-1088.

Full Product Information including Boxed Warning and Medication Guide has been provided to your doctor.



References: 1. Abrams P, et al. *Neurourol Urodyn*. 2010;29(1):213-240. 2. Chancellor MB, et al. *Am J Phys Rehabil*. 2006;85(6):536-545. 3. Fowler CJ, et al. *Nat Rev Neurosci*. 2008;9(6):453-466. 4. *Mosby's Dictionary of Medicine, Nursing & Health Professions*. 7th ed. Myers T, ed. St. Louis, MO: Mosby Elsevier; 2006. 5. Abrams P, et al. *Urology*. 2003;61(1):37-49. 6. Kershen RT. *Curr Urol Rep*. 2009;10(5):352-361. 7. Ellsworth P, et al. *Urol Nurs*. 2010;30(1):29-38, 53. 8. Wyndaele JJ, et al. *Neurourol Urodyn*. 2010;29(4):662-669. 9. Campbell JD, et al. *BMC Urol*. 2009;9:18. 10. BOTOX® Prescribing Information, August 2011.



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MEDICATION GUIDE
BOTOX®
BOTOX® Cosmetic
(Boe-tox)
(onabotulinumtoxinA)
for Injection

Read the Medication Guide that comes with **BOTOX** or **BOTOX Cosmetic** before you start using it and each time it is given to you. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information I should know about BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic may cause serious side effects that can be life threatening, including:

- **Problems breathing or swallowing**
- **Spread of toxin effects**

These problems can happen hours, days, to weeks after an injection of BOTOX or BOTOX Cosmetic. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX or BOTOX Cosmetic:

1. Problems swallowing, speaking, or breathing. These problems can happen hours, days, to weeks after an injection of BOTOX or BOTOX Cosmetic

- usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with **BOTOX** or **BOTOX Cosmetic**.
- People with certain breathing problems may need to use muscles in their neck to help them breathe. These people may be at greater risk for serious breathing problems with **BOTOX** or **BOTOX Cosmetic**.
 - Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving **BOTOX** or **BOTOX Cosmetic** have the highest risk of getting these problems.

2. Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:

- loss of strength and muscle weakness all over the body
- double vision
- blurred vision and drooping eyelids
- hoarseness or change or loss of voice (dysphonia)
- trouble saying words clearly (dysarthria)
- loss of bladder control
- trouble breathing
- trouble swallowing

These symptoms can happen hours, days, to weeks after you receive an injection of **BOTOX** or **BOTOX Cosmetic**.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving **BOTOX** or **BOTOX Cosmetic**?"

There has not been a confirmed serious case of spread of toxin effect away from the injection site when **BOTOX** has been used at the recommended dose to treat chronic migraine, severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX Cosmetic** has been used at the recommended dose to treat frown lines.

What are BOTOX and BOTOX Cosmetic?

BOTOX is a prescription medicine that is injected into muscles and used:

- to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease.
- to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day.
- to treat increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

BOTOX Cosmetic is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary).

It is not known whether **BOTOX** is safe or effective in people younger than:

- 18 years of age for treatment of urinary incontinence
- 18 years of age for treatment of chronic migraine
- 18 years of age for treatment of spasticity
- 16 years of age for treatment of cervical dystonia
- 18 years of age for treatment of hyperhidrosis
- 12 years of age for treatment of strabismus or blepharospasm

BOTOX Cosmetic is not recommended for use in children younger than 18 years of age.

It is not known whether **BOTOX** and **BOTOX Cosmetic** are safe or effective to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine).

It is not known whether **BOTOX** and **BOTOX Cosmetic** are safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

Who should not take BOTOX or BOTOX Cosmetic?

Do not take **BOTOX** or **BOTOX Cosmetic** if you:

- are allergic to any of the ingredients in **BOTOX** or **BOTOX Cosmetic**. See the end of this Medication Guide for a list of ingredients in **BOTOX** and **BOTOX Cosmetic**.
- had an allergic reaction to any other botulinum toxin product such as *Myobloc*®, *Dysport*®, or *Xeomin*®
- have a skin infection at the planned injection site
- are being treated for urinary incontinence and have a urinary tract infection (UTI)
- are being treated for urinary incontinence and 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 taking BOTOX or BOTOX Cosmetic?

Tell your doctor about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"
- have allergies to any botulinum toxin product

- had any side effect from any botulinum toxin product in the past
- have or have had a breathing problem, such as asthma or emphysema
- have or have had swallowing problems
- have or have had bleeding problems
- have plans to have surgery
- had surgery on your face
- have weakness of your forehead muscles, such as trouble raising your eyebrows
- have drooping eyelids
- have any other change in the way your face normally looks
- 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** or **BOTOX Cosmetic** can harm your unborn baby.
- are breast-feeding or plan to breastfeed. It is not known if **BOTOX** or **BOTOX Cosmetic** passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products. Using **BOTOX** or **BOTOX Cosmetic** 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 or BOTOX Cosmetic in the past.**

Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin, such as *Myobloc*[®] (rimabotulinumtoxinB), *Dysport*[®] (abobotulinumtoxinA), or *Xeomin*[®] (incobotulinumtoxinA) in the past. Be sure your doctor knows 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 anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners)

Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take BOTOX or BOTOX Cosmetic?

- **BOTOX** or **BOTOX Cosmetic** is an injection that your doctor will give you.
- **BOTOX** is injected into your affected muscles, skin, or bladder.
- **BOTOX Cosmetic** is injected into your affected muscles.
- Your doctor may change your dose of **BOTOX** or **BOTOX Cosmetic**, until you and your doctor find the best dose for you.
- **Your doctor will tell you how often you will receive your dose of BOTOX or BOTOX Cosmetic injections.**

What should I avoid while taking BOTOX or BOTOX Cosmetic?

BOTOX and **BOTOX Cosmetic** may cause loss of strength or general muscle weakness, or vision problems within hours to weeks of taking **BOTOX** or **BOTOX Cosmetic**. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.** See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

What are the possible side effects of BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic can cause serious side effects. See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

Other side effects of BOTOX and BOTOX Cosmetic 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, and dry eyes.
- urinary tract infection in people being treated for urinary incontinence
- inability to empty your bladder on your own and are being treated for urinary incontinence.
- allergic reactions. Symptoms of an allergic reaction to **BOTOX** or **BOTOX Cosmetic** may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **BOTOX** and **BOTOX Cosmetic**. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about BOTOX and BOTOX Cosmetic:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about **BOTOX** and **BOTOX Cosmetic**. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about **BOTOX** and **BOTOX Cosmetic** that is written for healthcare professionals. For more information about **BOTOX** and **BOTOX Cosmetic** call Allergan at 1-800-433-8871 or go to www.BOTOX.com.

What are the ingredients in BOTOX and BOTOX Cosmetic?

Active ingredient: botulinum toxin type A

Inactive ingredients: human albumin and sodium chloride

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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