

Informed consent for BOTOX[®] for overactive bladder (OAB) patients

Your doctor has recommended management of your OAB with BOTOX[®]. While the majority of these treatments are helpful in your specific diagnostic case, we like to notify our patients of the most common side effects. If you have symptoms that are bothersome, please notify the office. We take caution to try and prevent side effects by using antibiotics, before and after treatment, and local anesthetics, to minimize the side effects both during and after the treatment.

BOTOX[®] product information

BOTOX[®] treatment works by calming the nerves that trigger the bladder muscle to become overactive, helping to:

- Reduce daily leakage episodes
- Reduce the number of times that patients need to empty their bladders daily

Every patient is unique, and results of BOTOX[®] treatment will vary from patient to patient. In 2 clinical trials, at week 12, adults using BOTOX[®] had fewer daily accidents than those who did not use BOTOX[®]. Patients should not expect to see results right away. One BOTOX[®] treatment can provide up to 6 months of improvement of OAB symptoms. As symptoms return, patients can talk to their doctor about repeating the procedure to help treat symptoms, but no sooner than 12 weeks from the prior treatment.

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[®].

Please refer to the Important Safety Information included on this form and talk with your doctor.

Please notify our staff if you are allergic to any medications prior to the procedure. 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.

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[®] (rimabotulinumtoxinB), Dysport[®] (abobotulinumtoxinA), or Xeomin[®] (incobotulinumtoxinA) 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.

Thank you for allowing us the opportunity to take care of you!

By signing the following consent, you acknowledge that you have read this document and agree to have the treatment performed.

Patient name _____ Date of birth _____

Medical record number _____

1. I hereby authorize _____ and/or _____
and/or such assistants and associates as may be selected by him/her/them to perform the following treatment(s) upon the patient.

Treatment(s): BOTOX[®] 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 medicine (anticholinergic) does not work well enough or cannot be taken.

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

Indication

BOTOX[®] 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[®] 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 reverse side.

CONTINUED ON REVERSE SIDE

2. I acknowledge that I have received no warranties or guarantees with respect to the benefits to be realized or consequences of the aforementioned treatment(s).
3. I have read the information sheet entitled (leave blank if no information sheet is provided):

4. I have also read the Product Information, Product Information Indications, and the Important Safety Information provided throughout this document.
5. I acknowledge that I have read and fully understand this document and give my consent voluntarily to have the treatment performed. I also acknowledge that if I have any questions, I have had the opportunity to have them answered by my physician/healthcare provider.

Patient/Authorized person signature

Date

Print name

Witness signature

Date

Print name

Physician signature

Date

Print name

IMPORTANT SAFETY INFORMATION (continued)

BOTOX® (onabotulinumtoxinA) 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.**

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.

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

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.

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 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® should be discontinued.

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®.

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).

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.**

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.

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.

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.

Please see accompanying Summary of Information about BOTOX®.



Informed consent for treatment

Patient name _____ Date of birth _____

Medical record number _____

1. **TREATMENT** I request that Dr. _____, as my physician, his/her associate, and other healthcare providers, as they deem necessary, treat my condition which has been explained to me as

2. **INFORMED CONSENT** I state that I am making an informed consent for the treatment. Specifically, my doctor has informed me about:

- My condition, problem, or diagnosis
- A description of the planned treatment and its purpose
- The indication(s) of the proposed treatment
- Benefits, risks, complications, and alternative treatment
- The expected outcome and its likelihood
- Who will perform the treatment

I understand there is no guarantee of success.

3. **ALLERGIES, MEDICAL CONDITIONS, AND MEDICATIONS** I have informed my doctor, to the best of my knowledge, of any known medical conditions or allergies to substances or drugs. I have also notified my doctor and/or his/her staff if I am on any blood thinners, such as aspirin, *Plavix*[®], *Trental*[®], *Coumadin*[®], *Aggrenox*[®], *Pradaxa*[®], or any drugs like ibuprofen or *Aleve*[®].

4. **EMPLOYEE EXPOSURES** In the event that a healthcare provider sustains exposure to my blood or body fluids, I consent to providing a blood sample, which may be tested for infectious disease.

I HAVE READ THIS CONSENT FORM, THE PRODUCT INFORMATION, PRODUCT INFORMATION INDICATION, AND THE IMPORTANT SAFETY INFORMATION PROVIDED OR PROVIDED THROUGH THIS CONSENT, AND HAVE HAD THE OPPORTUNITY TO DISCUSS ITS CONTENTS WITH MY DOCTOR TO MY SATISFACTION.

Patient/Authorized person signature

Date

Witness signature

Date

Indication

BOTOX[®] 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[®] 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 reverse side.

IMPORTANT SAFETY INFORMATION (continued)

BOTOX® (onabotulinumtoxinA) 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.**

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.

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

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.

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 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® should be discontinued.

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®.

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).

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.**

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.

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.

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.

Please see accompanying Summary of Information about BOTOX®.

BOTOX[®] for overactive bladder (OAB) patients: Informed consent form and treatment-specific information for patients

Patient name _____ Date of birth _____

Medical record number _____

By signing the consent on the reverse side, you acknowledge that you have read this document and agree to have the following treatment performed.

Treatment(s): BOTOX[®] 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 medicine (anticholinergic) does not work well enough or cannot be taken.

My doctor has explained to me that he/she is going to insert a small tube (cystoscope) into my urethra so he/she can examine my urethra and bladder. BOTOX[®] will then be injected into multiple areas in the bladder muscle. If the treatment is performed, I understand that any of the following could possibly happen:

- If not able to pass urine, I will have to self-catheterize as previously instructed
- I may develop a bladder infection and will be given a prescription for antibiotics to take after the treatment
- I may experience urinary incontinence, which is a sign that I need to contact my doctor immediately, as it may be a sign of distant spread of toxin effect
- I may experience bleeding, which will generally be mild
- I may experience slight discomfort in the urethra or bladder

I have informed my healthcare provider to the best of my knowledge of any health conditions I have, including the following:

- A disease that affects the muscles and nervous system (such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome)
- A breathing problem, such as asthma or emphysema, now or in the past
- Swallowing problems, now or in the past
- Bleeding problems, now or in the past
- Plans to have surgery
- Surgery on the face
- Weakness of forehead muscles
- Trouble raising eyebrows
- Other (if none, leave blank) _____
- Drooping eyelids
- Any other abnormal facial change
- Symptoms of a urinary tract infection (UTI) and am being treated for urinary incontinence (symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever)
- Problems emptying my bladder on my own and am being treated for urinary incontinence
- Am pregnant or plan to become pregnant (it is not known if BOTOX[®] can harm an unborn baby)
- Am breastfeeding or plan to (it is not known if BOTOX[®] passes into breast milk)

I have informed my healthcare provider to the best of my knowledge of any known allergies or reactions to substances or drugs, including the following:

- Allergies to any botulinum toxin product
- Side effects from any botulinum toxin product in the past
- Other (if none, leave blank) _____

Indication

BOTOX[®] 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[®] 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 reverse side.

CONTINUED ON REVERSE SIDE

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

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

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.

NOTE: Patients need to STOP taking blood thinners such as *Coumadin*®, warfarin, *Aggrenox*®, *Plavix*®, ibuprofen, or *Aleve*® at least 3 days before treatment or as directed by their physician.

By signing below, I agree to the following:

- My physician and/or the assistant have explained the treatment to me and what could possibly happen after the treatment
- I have been told of other forms of treatment or nontreatment
- I understand that BOTOX® may not cure my urinary problem
- I agree to have a BOTOX® treatment done today
- I have read the Product Information, Product Information Indication, and the Important Safety Information provided to me

Patient/Authorized person signature

Date/Time

Print name

Witness signature

Date/Time

Print name

IMPORTANT SAFETY INFORMATION (continued)

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.**

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.

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

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.

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 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® should be discontinued.

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®.

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).

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.**

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.

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.

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.

Please see accompanying Summary of Information about BOTOX®.



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 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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