

## **BOTOX® bladder injection**

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 leakage or wetting accidents; urgency and frequency in adults when another type of medication (anticholinergic) does not work well enough or cannot be taken

To treat leakage of urine (incontinence) in adults, with overactive bladder due to neurologic condition, who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication

One BOTOX® treatment can last up to 6 months before the effects wear off. As your symptoms return, talk to your doctor about repeating the treatment to help control your symptoms, but no sooner than 12 weeks from prior treatment.

### **Here's what you can expect before your BOTOX® treatment:**

You should not receive BOTOX® if you have a urinary tract infection. You will be given a preventative antibiotic to take prior to your BOTOX® appointment to help prevent infection

You will be given a numbing agent, maybe in combination with a sedative, to keep you relaxed and comfortable during the procedure

Once your bladder is numb, a small tube called a cystoscope is inserted through the urethra (the natural opening where the urine comes out)

BOTOX® goes through the cystoscope and is administered with a small needle into multiple areas of your bladder muscle

The treatment itself only takes approximately 30 minutes. Then you will be observed for about 30 minutes, and your doctor will make sure you have emptied your bladder before you leave the office. You should not experience significant pain after 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.

### **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, 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.

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.

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 catheterization post-treatment, if required, should be considered for treatment.

Patients treated for overactive bladder due to neurologic condition

In clinical trials, 30.6% of patients (33/108) who were not using clean intermittent catheterization (CIC) prior to injection, required catheterization for urinary retention following treatment with BOTOX® 200 Units as compared to 6.7% of patients (7/104) treated with placebo. The median duration of post-injection catheterization for these patients treated with BOTOX® 200 Units (n=33) was 289 days (minimum 1 day to maximum 530 days) as compared to a median duration 358 days (minimum 2 days to maximum 379 days) for patients receiving placebo (n=7). Among patients not using CIC at baseline, those with MS were more likely to require CIC post-injection than those with SCI.

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. They include itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

Other side effects of BOTOX® 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. Other side effects 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