A guide for patients being treated with BOTOX[®] (Urology)









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Important

Like all medicines, BOTOX® can have side effects. We strongly advise you to read the Patient Information Leaflet that comes with the medicine before treatment starts. Please ask your doctor or nurse to provide you with this leaflet, or you can read it online at: www.maltamedicineslist.com

What is BOTOX®?

 $\mathsf{BOTOX}^{\circledcirc}$ is a prescription medicine that contains a tiny amount of a protein, which would do harm in large amounts, but in the very tiny amounts that doctors use, can be beneficial.

BOTOX® has been available worldwide for over 20 years and is used in the treatment of a number of medical conditions.

How may BOTOX® help me?

BOTOX® may help you if you have leakage of urine due to uncontrolled contractions of the bladder wall (idiopathic overactive bladder) or due to bladder problems associated with spinal cord injury or multiple sclerosis (neurogenic overactive bladder). It helps an overactive bladder wall to relax, which in turn can help stop many of the symptoms that people find so upsetting in adults when another type of medicine (anticholinergics) does not work well enough or cannot be taken.

BOTOX® can

- Reduce the amount of urine leakage accidents
- Reduce the feeling of needing to go to the toilet very suddenly
- Reduce how often you feel the need to pass urine
- Increase the amount of urine that the bladder can hold

Improvement can be expected within 2 weeks after the injection and the effect typically lasts 8–10 months for neurogenic overactive bladder and 5–6 months for idiopathic overactive bladder. After this, you and your doctor can decide whether you should have another treatment with BOTOX®.

What does the treatment involve?

Before your treatment

Before recommending BOTOX®, your doctor will have carried out a number of tests to check that it is a suitable treatment for you. They will also ask you whether you have ever used clean intermittent catheterisation (CIC), also known as self-catheterisation, as you may not be able to receive treatment if you are not able or willing to use CIC.

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You should not receive treatment with BOTOX® if:

- You have had a bad reaction to botulinum toxin type A treatment in the past
- You have an infection at or around any of the areas to be injected
- You are pregnant or breast-feeding

If you decide to go ahead with the treatment, your doctor will also need to check that you do not have a urinary tract infection (UTI) or urinary retention at the time of treatment.

You will also need a short course of antibiotics before your treatment to help prevent urinary tract infection. If you are taking anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners), your doctor will talk to you about temporarily stopping these.

How is the treatment given?

Your treatment with BOTOX® will take place in a hospital or clinic.

Your doctor will discuss with you the options of a general or local anaesthetic to minimise the discomfort of the procedure. Local anaesthetic would be administered via a catheter into your bladder.

To put the BOTOX® into your bladder, your doctor will use a cystoscope. This is a fine tube, containing a tiny camera that enables doctors to see inside the bladder.

Your doctor will inject tiny amounts of BOTOX® into the muscle of your bladder. The whole procedure should be over in about 30 minutes.

Most people who have had BOTOX® treatment in the bladder describe it as 'uncomfortable' but not painful.

What happens after treatment?

It is important that you follow your doctor's care advice after you have received BOTOX® treatment in the bladder. You will be given another short course of antibiotics after your treatment to help prevent UTI.

Prior to your BOTOX® treatment, you may have been using CIC. If you were, you'll get follow-up care instructions and an appointment depending on the hospital's own policy.

If you were not using CIC before BOTOX® treatment

- Your doctor may wish to see you within 2 weeks of injection to check that your bladder is emptying properly
- You will be asked to pass urine and will then have the volume of urine left in your bladder measured using ultrasound
- Hopefully your bladder will be emptying well; but if it isn't, your doctor will talk to you about what you can do
- Your doctor will tell you if you need to return for the same test again over the next 12 weeks
- You must contact your doctor if at any time you are unable to pass urine

Following treatment, your doctor will assess whether you need to begin using CIC. If you do, this is not something to worry about and you will be instructed on how to do this.

Once you're able to manage CIC, you'll probably only need to go to the toilet to empty your bladder every 3-4 hours, when it's convenient for you. Your doctor will see you after your treatment to assess how long you need to use CIC.

What should I look out for after treatment?

Like all medicines, BOTOX® can cause side effects, although not everybody gets them. In general, side effects occur within the first few days following injection and last only for a short time. In rare cases, they may last for several months or longer. The side effects that have been reported following treatment with BOTOX® are described in the Patient Information Leaflet that can be found at www.maltamedicineslist.com.

The most common thing you might notice is blood in your urine and some bladder pain immediately after the procedure. This should pass fairly quickly and you can take simple pain-relieving medicine, which will be discussed with you before you go home.

Important

Side effects related to the spread of toxin distant from the site of administration have been reported very rarely with botulinum toxin (e.g. exaggerated muscle weakness, difficulty in swallowing, food or liquid accidentally going into the lungs and pneumonia).

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You should contact your doctor immediately if you experience any of the following:

- · Difficulty in breathing, swallowing or speaking
- Urinary tract infection (a burning sensation on passing urine and a temperature over 38°C)
- Inability to empty your bladder (urinary retention)
- Severe allergic reaction (hives, swelling including swelling of the face/ throat, wheezing, feeling faint and shortness of breath)

If you notice any side effects not listed in this booklet or the Patient Information Leaflet, please tell your doctor.

When will I need to see my doctor again for re-treatment?

Your doctor will tell you when you need to return for an appointment so they can follow up your progress over the longer term.

They may arrange an appointment for you after a few weeks to see how you are getting on. Or they may tell you to book an appointment to see them when the effects of BOTOX® start to wear off e.g. you experience an increase in urine leakage or the increasing urge to pass urine.

Where can I find out more information?

If you have any questions about your treatment, please ask your doctor or nurse. Why not write down any questions you have beforehand to make sure that all your questions are answered.

Your doctor should also give you a copy of the Patient Information Leaflet which can probably answer most of your queries. If your doctor does not give you a copy of this, you can read it online at: www.maltamedicineslist.com.

Patient organisations

Malta Health Network

MHN
Patients Rights
Malta
www.maltahealthnetwork.org
info@maltahealthnetwork.org

Multiple Sclerosis Society of Malta

www.msmalta.org.mt maltams@gmail.com

Your guide to treatment with BOTOX®

(botulinum toxin type A)

Suspected side effects or medication errors should be reported since these increase the available knowledge on the medicine.

Side-effects or medication errors can be reported to the Medicines Authority by filling in a form online at www.medicinesauthority.gov.mt/adrportal or at 203, Level 3 Rue D'Argens Gzira GZR1368

Alternatively they may be reported to Vivian Corporation, 29, Tower Street, Msida MSD1824 or by phoning +35621344610

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