

A guide for patients treated with BOTOX®

What is BOTOX®?

BOTOX®, a prescription medicine, is used to treat a number of conditions within the body. It works by partially blocking nerve impulses and the effect for the patient depends upon where it is injected. If injected into a muscle (including the bladder) it will reduce excessive contractions of that muscle. If injected into the skin in the underarm area it will reduce how much sweat is produced.

For more information on BOTOX®, please refer to the Patient Information Leaflet. Your doctor can give you a copy of this leaflet.

Following your treatment your doctor or nurse may ask you to stay at the clinic for a short time, to check that you are comfortable.

What should I look out for after treatment?

Like all medicines, BOTOX® can cause adverse events, although not everybody gets them. Following treatment you may experience local reactions at the site of injection (e.g. bumps/bruising following injection under the skin or into muscle; or blood in your urine and/or bladder pain following injection into the bladder). This should pass fairly quickly and you can take simple pain relieving medicine.

In general, adverse events occur within the first few days following injection and last only for a short time. In rare cases, adverse events may last for several months or longer.

You should contact your doctor immediately if you or your child experience any of the following after treatment:

1) For all treated conditions:

- Adverse events, related to BOTOX® spread, distant from the site of injection. These have been reported very rarely (e.g. exaggerated muscle weakness, difficulty in breathing, swallowing or speaking, food or liquid accidentally going into the lungs and pneumonia).
- Severe allergic reactions (hives, swelling including swelling of the face/throat, wheezing, feeling faint and shortness of breath)

2) For cervical dystonia and chronic migraine:

- Difficulty in swallowing

3) For bladder conditions:

- Burning sensation on passing urine and a temperature over 38°C following treatment for overactive bladder.
NOTE: If you have been given antibiotics prior to treatment, you will be required to continue taking these for a few days following treatment.
- Inability to pass urine. Your doctor will decide if you need to start using a catheter.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Medicines Authority by filling in a form online at www.medicinesauthority.gov.mt/adportal 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 calling +356 21344610. By reporting side effects you can help provide more information on the safety of this medicine.

This is the emergency telephone number you should call if you experience any severe adverse events or reactions: