

Patient Education Leaflet

HOW SAFE IS BOTOX® LONG-TERM?

BOTOX® treatment has been used in patients to manage various conditions for over 10 years in the UK and for well over 15 years around the world. For many conditions, the dose used by doctors has been significantly greater than that used by those treating cosmetic patients.

A recent analysis of BOTOX® studies has followed over 2000 patients for an average of 12 years of treatment and has concluded that BOTOX® has a favourable safety and tolerability profile.

HOW DO I KNOW I AM RECEIVING BOTOX® AND NOT A SUBSTITUTE PRODUCT?

BOTOX® is a registered trademark of Allergan, Inc. The BOTOX® product is packaged in a glass vial with a purple lid labelled as BOTOX® and an Allergan hologram on the vial. You may wish to ask your injector to confirm that this is the product he/she is using for your treatment.

Further detailed information can be obtained from the Patient Information Leaflet in the product pack or by contacting Medical Information at Allergan Ltd on 01494 427026.



BOTOX®
Botulinum Toxin Type A
Purified Neurotoxin Complex

Your doctor has recommended that you may be suitable for injections of BOTOX® and is therefore providing you with this leaflet about BOTOX® treatment. This leaflet has been produced to give additional information to patients. Further information should be obtained from the Patient Information Leaflet in the product pack.

If you have additional questions relating to BOTOX® treatment please ask your doctor.

WHAT IS BOTOX®?

BOTOX® contains a highly purified protein. When injected into muscles BOTOX® relaxes the target area resulting in a reduced muscle activity.

WHO MAKES BOTOX®?

BOTOX® is manufactured by Allergan Pharmaceuticals Ireland, Westport, County Mayo, Ireland. The product licence holder is Allergan Ltd, Coronation Road, High Wycombe, Bucks HP12 3SH.

FOR WHAT USES IS BOTOX® CURRENTLY APPROVED (LICENSED) IN THE UK?

BOTOX® has received regulatory approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) for the use of BOTOX® in the following conditions:

- Muscle stiffness (spasticity) following a stroke in adults
- Muscle stiffness (spasticity) associated with cerebral palsy in children
- Dystonia (muscle jerking) of the neck (cervical dystonia)
- Muscle spasm of the face (hemifacial dystonia)
- Rapid blinking of the eye muscle (blepharospasm)
- Excessive sweating of the armpits (hyperhidrosis)

BOTOX® is not licensed in the UK for use in cosmetic treatment, therefore, if your doctor has recommended this treatment for you, the following information may be of help to you:

- A doctor is able to recommend and prescribe any prescription medicine even it is not approved for the use he/she is considering
- You should be provided with adequate information about the efficacy and safety of the product and consent in writing to receiving this treatment only when you have fully understood the likely benefits and likely side effects
- Once you have agreed on your treatment with your doctor, he/she may ask another healthcare professional to administer (inject) on his/her behalf
- You should be reassured that the healthcare professional treating you is experienced in providing the specific treatment and is able to provide you with the necessary after-care advice and follow-up

WHAT SIDE EFFECTS MAY I EXPECT FOLLOWING BOTOX® TREATMENT?

As with all prescription medicines, BOTOX® can cause side effects and your doctor will advise you about these in more detail.

Most side effects experienced by patients are short-lived and are linked to the injections e.g. pain on injection, redness, swelling etc.

Other side effects such as ptosis (drooping of the upper eyelid), whilst still temporary in nature can be caused by a spread of the injection into nearby muscles.

Choosing an experienced injector will minimise (but not eliminate) the risk of such side effects.

A detailed list of side effects can be obtained from the Patient Information Leaflet in the product pack. Please ask your physician for this leaflet.

WILL THE TREATMENT HURT?

The needles used are very fine so most people experience only mild discomfort. It is uncommon for pain relief to be required although some physicians suggest the use of a topical anaesthetic cream before treatment.

HOW LONG WILL IT TAKE TO WORK?

You may start to notice an effect after 1-2 days. However, this varies by patient. The full effect can take up to 2 weeks following treatment.

HOW LONG WILL THE EFFECTS OF BOTOX® LAST?

Duration of effect varies by patient and depends on the severity of the condition being treated. Your physician will give advice on realistic expectations for you as an individual patient.

HOW REGULARLY SHOULD I BE REVIEWED?

As with all prescription medicines, your physician will advise when he/she will need to review your treatment.