



A guide for patients being treated with VISTABEL[®] (Botulinum toxin type A)

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How can this information leaflet help you?

Your doctor has prescribed treatment with VISTABEL® (Botulinum toxin type A) for the temporary improvement in the appearance of your glabellar lines seen at maximum frown and/or crow's feet lines seen at maximum smile.

This information booklet contains additional information concerning this treatment and its follow-up.

As with any other medical treatment, do not hesitate to speak to your doctor about your treatment. If you have any questions, refer to the package leaflet.

You are going to be given an injection of VISTABEL®, please notify your doctor immediately if you suffer from any of the following signs or symptoms following treatment:

- Difficulty swallowing
- Difficulty breathing
- Difficulty speaking
- Muscle weakness
- Allergic reaction (swelling of face or throat, hives, wheezing, feeling faint, shortness of breath)

1. What is VISTABEL®?

Nerve endings release a chemical substance, acetylcholine, which transmits contraction information to the muscle.

VISTABEL® is a type A botulinum toxin whose role is to temporarily block the release of acetylcholine. The muscle is then relaxed and the wrinkle is reduced.

Frown lines are caused by the contraction of three muscles, the procerus, located between the eyebrows, and the corrugators above each eyebrow. VISTABEL® is injected into these different muscles that cause these lines.

Crow's feet lines are caused by the contraction of the lateral orbicularis oculi muscle at the side of the eye. VISTABEL® is injected into different areas of this muscle.

2. What are the side effects?

Like all medicines, VISTABEL® can have side effects, although not everybody gets them.

Side effects usually occur within the first few days of injection and are temporary.

- The most common side effects following treatment for glabellar lines are headache, drooping of the eyelid, skin redness, skin tightness, local muscle weakness, facial pain, numbness and nausea (feeling sick).
- For crow's feet lines, the most common side effect is swelling of the eyelid.

Other side effects may be associated with the injection (injection site bleeding, bruising, redness, pain, burning, stinging and swelling).

Adverse reactions possibly related to the spread of toxin distant from the site of administration have been reported very rarely with botulinum toxin (e.g. muscle weakness, difficulty to swallow, constipation or pneumonia due to unwanted food or liquid in the airways, which can be fatal). Injection of VISTABEL® is not recommended in patients with a history of dysphagia (difficulty to swallow) and impaired swallowing.

Tell your doctor immediately if any of the following signs or symptoms appear:

- Difficulty swallowing
- Difficulty breathing
- Difficulty speaking
- Muscle weakness
- Allergic reaction (swelling of face or throat, hives, wheezing, feeling faint, shortness of breath)

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/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 calling +356 21344610. By reporting side effects you can help provide more information on the safety of this medicine.

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