Glabellar Lines Treatment with Azzalure®

(Botulinum toxin A)

Important information about treatment with Azzalure



Important information about treatment with Azzalure

What Azzalure is and what is it used for?

Azzalure contains a substance, botulinum toxin A, which causes muscles to relax. Azzalure acts at the junction between the nerves and muscle to prevent the release of a chemical messenger called acetylcholine from the nerve endings. This prevents muscles from contracting. The muscle relaxation is temporary and gradually wears off.

Some people are distressed when lines appear on their face. Azzalure can be used in adults under 65 years to temporarily improve the appearance of any moderate to severe glabellar lines. These are the vertical frown lines between the eyebrows.



What are the risks and side effects of botulinum toxin?

Like all medicines, Azzalure can cause side effects, although not everybody gets them

Seek urgent medical help if:

- · You have difficulties breathing, swallowing or speaking
- Your face swells or skin goes red or you get an itchy lumpy rash. This may mean you are having an allergic reaction to Azzalure

Tell your doctor if you notice any of the following side effects:

Very Common (affects more than 1 user in 10)

- Redness, swelling, irritation, rash, itching, tingling, pain, discomfort, stinging or bruising at the site of the injection
- Headache

Common (affects 1 to 10 users in 100)

- Tired eyes or dim vision, drooping of the upper eyelid, swelling of the eyelid, watering eyes, dry eye, twitching of muscles around the eye
- Facial paralysis

Uncommon (affects 1 to 10 users in 1,000)

- · Disturbed, blurred or double vision
- Dizziness
- · Itching, rash
- · Allergic reactions, see above
- · Eye movement disorder

Rare (affects 1 to 10 users in 10,000)

Itchy and lumpy rash

Usually these side effects occur within the first week following injections, do not last long and are mild to moderate in severity.

The risk of potentially dangerous side effects is very low but may be increased in patients with swallowing disorders, certain neuromuscular disorders, pre-existing pulmonary problems or in patients treated with medications which can amplify the effect of botulinum toxin. It is important that you inform your treating physician if you suffer at present or suffered in the past from any diseases and if you are being treated with any medication.

The following side effects are of particular importance and you need to seek urgent medical help in case you noticed them:

- · You have difficulties breathing, swallowing or speaking
- Your face swells or skin goes red or you get an itchy lumpy rash. This may mean you are having an allergic reaction to Azzalure®



If you consult physicians of other specialities for different reasons please inform them about treatment with botulinum toxin.

Your information leaflet in the medicine pack tells you more about the possible side effects.

If you have any questions or worries talk to your doctor.

Read the package leaflet as this contains full details about Azzalure.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For further information, please contact your doctor