PACKAGE LEAFLET: INFORMATION FOR THE USER
Azzalure, 125 Speywood units, powder for solution for injection
(botulinum toxin type A)

Read all of this leaflet carefully, before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See Section 4.

In this leaflet:

1. WHAT AZZALURE IS AND WHAT IT IS 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 (the vertical frown lines between the eyebrows) and lateral canthal lines (crow's feet lines).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AZZALURE

Do not have an Azzalure injection if:

- You are allergic to *Clostridium botulinum* toxin A or any of the other ingredients of this medicine (listed in section 6)
- You have an infection at the proposed site of injection
- You have myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis.

Warnings and precautions

Talk to your doctor before you have the Azzalure injection if:

- You have any neuromuscular disorders
- You often have difficulty swallowing food (dysphagia)
- You find that you often have problems with food or drink getting into your airways causing you to cough or choke
- You have inflammation at the proposed site of injection
- The muscles at the proposed site of injection are weak
- You suffer from a bleeding disorder which means that you continue to bleed for longer than normal, such as haemophilia (hereditary bleeding disorders caused by deficiencies of clotting factor)

- You have had surgery on your face, or are likely to undergo facial or other types of surgery soon
- You have already had other botulinum toxin injections
- You had no significant improvement of your lines after your last treatment with botulinum toxin.

This information will help your doctor to make an informed decision about the risk and benefit of your treatment.

Special warnings:
Very rarely, the effect of botulinum toxin may result in muscle weakness away from the site of injection.

When botulinum toxins are used at more frequent intervals than 12 weeks or at higher doses to treat other conditions, antibody formation has been noted rarely in patients. The formation of neutralising antibodies may reduce the effectiveness of treatment.
If you are seeing a doctor for any reason, make sure that you tell them that you have been treated with Azzalure.

Children and adolescents
Azzalure is not indicated for subjects under the age of 18 years.

Other medicines and Azzalure
Tell your doctor if you are using, have recently used or might use any other medicines, as Azzalure may affect other medicines, especially:

- Antibiotics for an infection (e.g. aminoglycosides, such as gentamicin or amikacin), or
- Other muscle relaxant drugs.

Azzalure with food and drink
You can have Azzalure injections either before or after eating or drinking.

Pregnancy and breast-feeding
You should not get Azzalure during pregnancy. Treatment with Azzalure is not recommended if you are breast-feeding.

If you are pregnant or planning to become pregnant, or if you are breast-feeding, ask your doctor for advice before taking any medicine.

Driving and using machines
You may experience temporary blurred vision or muscle weakness following treatment with Azzalure. If affected, do not drive or use machinery.

3. HOW TO USE AZZALURE

Azzalure should only be administered by physicians with appropriate qualifications and expertise in this treatment and having the required equipment.

Your doctor will prepare and give the injections. A vial of Azzalure should be used only for you and only for a single treatment session.

The effect of the treatment should be noticeable within a few days after injection.

The interval between treatments with Azzalure will be decided by your doctor. You should not have treatment more often than every 12 weeks.

Azzalure is not indicated for patients under the age of 18.

If you receive more Azzalure than you should
If you are given more Azzalure than you need then muscles other than the ones that were injected may begin to feel weak. This may not happen straight away. If this happens, speak to your doctor immediately.

4. POSSIBLE SIDE EFFECTS

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:
For glabellar lines:
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
- Temporary facial paralysis

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

- Disturbed, blurred or double vision
- Dizziness
- Itching, rash
- Allergic reactions

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

- Itchy and lumpy rash
- Eye movement disorder

For lateral canthal lines:
Common (affects 1 to 10 users in 100)

- Headache
- Swelling of the eyelid
- Bruising, itching and swelling around the eyes
- Drooping of the upper eyelid
- Temporary facial paralysis

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

- Dry eye

Usually these side effects have occurred within the first week following injections and did not last long. They were usually mild to moderate in severity.

Very rarely, side effects experienced in muscles other than the ones that were injected have been reported with botulinum toxin. These include excessive muscle weakness, difficulty swallowing, due to coughing and choking when swallowing (if food or liquid enters your airway as you attempt to swallow, respiratory problems can occur, such as lung infections). If this happens, speak to your doctor immediately.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

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5. CONTENTS OF THE PACK AND OTHER INFORMATION

What Azzalure contains

- The active substance is *botulinum* toxin type A*. One vial contains 125 Speywood units.
- The other ingredients are human albumin 200g/L and lactose monohydrate.

**Clostridium botulinum* (a bacteria) toxin A haemagglutin complex.

The Speywood units of Azzalure are specific to the product and are not interchangeable with other treatments containing botulinum toxin.

What Azzalure looks like and contents of the pack
Azzalure is a powder for solution for injection. It comes in a pack size of 1 or 2 vials.
Azzalure is a white powder.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
For UK: Ipsen Limited, 190 Bath Road, Slough, Berkshire, SL1 3XE, United Kingdom.
For Ireland: Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France.

Manufacturer:
For UK: Ipsen Biopharm Limited, Ash Road, Wrexham Industrial Estate, Wrexham, LL13 9UF, UK.
For Ireland: Ipsen Manufacturing Ireland Limited, Blanchardstown Industrial Park, Blanchardstown, Dublin 15, Ireland.