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, pharmacist or other healthcare practitioner.
- If you get any side effects, talk to your doctor, pharmacist or other healthcare practitioner. 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
2. What you need to know before you use Azzalure
3. How to use Azzalure
4. Possible side effects
5. How to store Azzalure
6. Contents of the pack and other information

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, pharmacist or other healthcare practitioner 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 or other healthcare practitioner to make an informed decision about the risk and benefit of your treatment.

When you are treated with Azzalure, your eyes may become dry. Azzalure may make your eyes blink less often or produce less tears, which could harm the surface of your eyes.

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, pharmacist or other healthcare practitioner 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, pharmacist or other healthcare practitioner for advice before taking any medicine.

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

3. HOW TO USE AZZALURE

Azzalure should only be administered by a doctor or other healthcare practitioner with appropriate qualifications and expertise in this treatment and having the required equipment.
Your doctor or other healthcare practitioner will prepare and give the injections. A vial of Azzalure should be used only for you and only for a single treatment session.
The recommended dose of Azzalure is:

- ***For glabellar lines:*** 50 units, injected as 10 units at each of 5 injection sites in your forehead in the area above your nose and eyebrows.
- ***For lateral canthal lines:*** 60 units, injected as 10 units at each of 6 injection sites in both crow's feet regions.

The units used for different botulinum toxin products are not the same. Azzalure Speywood units are not interchangeable with other botulinum toxin products.
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 or other healthcare practitioner. 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 or other healthcare practitioner 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 or other healthcare practitioner 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

Not known (frequency cannot be estimated from the available data):

- Numbness
- Muscle wasting
- Generalised weakness
- Fatigue
- Flu-like symptoms

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

Not known (frequency cannot be estimated from the available data):

- Allergic reactions
- Numbness
- Muscle wasting
- Generalised weakness
- Fatigue
- Flu-like symptoms

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 or other healthcare practitioner immediately.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or other healthcare practitioner. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE AZZALURE

Keep Azzalure out of the sight and reach of children.

Your doctor should not use Azzalure after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store Azzalure in a refrigerator (2˚C - 8˚C). Unopened vials of Azzalure can be used following a single exposure to temperatures up to 25°C for up to 72 hours, after which time the unopened vial should be stored in a refrigerator (2°C - 8°C) for the duration of shelf-life. Do not freeze.

Your doctor will dissolve Azzalure into a liquid solution for injection.
Chemical and physical in-use stability has been demonstrated for 24 hours between 2 - 8°C. From a microbiological point of view, unless the method of reconstituting precludes the risks of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

6. 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 haemagglutinin 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:
Ipsen Limited, 5th Floor, The Point, 37 North Wharf Road, Paddington, London, W2 1AF, United Kingdom.

Manufacturer:
Ipsen Biopharm Limited, Ash Road, Wrexham Industrial Estate, Wrexham, LL13 9UF, UK.

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If you would like any more information, or would like the leaflet in a different format, please contact Galderma (UK) Limited, tel. +44 (0) 300 3035674.
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The following information is intended for healthcare professionals only:

Posology and method of administration:
Please refer to section 3 of the Patient Information Leaflet.

Special precautions for disposal and other handling:
The instructions for use, handling and disposal should be strictly followed.

Reconstitution should be performed in accordance with good practice rules, particularly in the respect of asepsis.

Azzalure has to be reconstituted with a sodium chloride 9 mg/ml (0.9 %) solution for injection.

As per the dilution table below, the requested amount of sodium chloride 9 mg/ml (0.9 %) solution for injection has to be drawn up into a syringe in order to obtain a reconstituted clear and colourless solution at the following concentration:

Amount of solvent added (0.9 % sodium chloride solution) to a 125 U vial	Resulting dose
0.63 ml	10 U per 0.05 ml
1.25 ml	10 U per 0.1 ml

The accurate measurement of 0.63 ml or 1.25 ml can be achieved using syringes graduated in 0.1 ml and 0.01 ml increments.

RECOMMENDATIONS FOR THE DISPOSAL OF CONTAMINATED MATERIALS

Immediately after use and prior to disposal, unused reconstituted Azzalure (in the vial or in the syringe) should be inactivated with 2 ml of dilute sodium hypochlorite solution at 0.55 or 1 % (Dakin's solution).

Used vials, syringes and materials should not be emptied and must be discarded into appropriate containers and disposed of in accordance with local requirements.

RECOMMENDATIONS SHOULD ANY INCIDENT OCCUR DURING THE HANDLING OF BOTULINUM TOXIN

- Any spills of the product must be wiped up: either using absorbent material impregnated with a solution of sodium hypochlorite (bleach) in case of the powder, or with dry, absorbent material in case of reconstituted product.
- The contaminated surfaces should be cleaned using absorbent material impregnated with a solution of sodium hypochlorite (bleach), then dried.
- If a vial is broken, proceed as mentioned above by carefully collecting the pieces of broken glass and wiping up the product, avoiding any cuts to the skin.
- If the product comes into contact with the skin, wash the affected area with a solution of sodium hypochlorite (bleach) then rinse abundantly with water.
- If product enters into contact with the eyes, rinse thoroughly with plenty of water or with an ophthalmic eyewash solution.

- If product enters into contact with a wound, cut or broken skin, rinse thoroughly with plenty of water and take the appropriate medical steps according to the dose injected.

These instructions for use handling and disposal should be strictly followed.