PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Alluzience, 200 Speywood units/ml, solution for injection

Clostridium botulinum toxin type A haemagglutinin complex

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.

What is in this leaflet

1. What Alluzience is and what it is used for

Alluzience contains the active substance botulinum toxin A, which causes muscles to relax. Alluzience 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.

The well-being of some people can be impacted when lines appear on their face. Alluzience is 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).

2. What you need to know before you use Alluzience

Do not have an Alluzience injection if:

- you are allergic to 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 Alluzience 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 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:
Side effects possibly related to the spread of toxin effect away from the site of injection have been reported very rarely with botulinum toxin (e.g. muscle weakness, difficulty swallowing or unwanted food or liquid in the airways).
Seek immediate medical attention if you experience difficulties in swallowing, speaking or breathing.

When botulinum toxins are used more than once every 3 months 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 Alluzience.

Children and adolescents

Alluzience is not recommended for use in patients under the age of 18 years.

Other medicines and Alluzience

Tell your doctor if you are using, have recently used or might use any other medicines. This is important because some of these medicines may increase the effect of Alluzience:
- antibiotics for an infection (e.g. aminoglycosides such as gentamicin or amikacin); or
- other muscle relaxant drugs.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Alluzience should not be used during pregnancy or if you are breast-feeding.

Driving and using machines

You may experience temporary visual disturbances or muscle weakness following treatment with Alluzience. If affected, do not drive or use machinery.

Alluzience contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. How to use Alluzience

Alluzience should only be administered by a doctor with appropriate qualifications and expertise in this treatment and having the required equipment.
Your doctor will give the injections. A vial of Alluzience should be used only for you and only for a single treatment session.

The recommended dose for glabellar lines is 50 Speywood units, injected as 10 Speywood units at each of 5 injection sites in your forehead in the area above your nose and eyebrows.
Doses recommended in Speywood units are different from other botulinum toxin preparations.
The effect of the treatment should be noticeable within a few days after injection, and could last for up to 6 months.
The interval between treatments with Alluzience will be decided by your doctor. You should not have treatment more often than every 3 months.

Use in children and adolescents

Alluzience is not recommended for use in patients under the age of 18 years.

If you receive more Alluzience than you should

If you are given more Alluzience than you need, muscles other than the ones that were injected may begin to feel weak. Excessive doses may cause paralysis of respiratory muscles. This may not happen straight away. If this happens, speak to your doctor immediately.
If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rarely (may affect up to 1 in 10,000 people), 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, 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.

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 a serious allergic reaction to Alluzience.

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

Very Common (may affect more than 1 in 10 people)
- Headache
- Injection site reactions (such as pain, tingling, bruising, redness, swelling, itching, rash, irritation, discomfort, stinging), generalised weakness and flu-like symptoms.

Common (may affect up to 1 in 10 people)
- Temporary facial paralysis
- Drooping of the upper eyelid, swelling of the eyelid, drooping of eyebrow, tired eyes or dim vision, dry eye, twitching of muscles around the eye, watering eyes.

Uncommon (may affect up to 1 in 100 people)
- Eyelid twitching, disturbed, blurred or double vision
- Eye allergy, hypersensitivity, rash.

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. You can also report side effects directly via the national reporting system listed in

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

5. How to store Alluzience

Keep this medicine out of the sight and reach of children.

Do not use Alluzience after the expiry date which is stated on the label.

Store Alluzience in a refrigerator (2˚C – 8˚C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

Once opened, the product should be used immediately.

6. Contents of the pack and other information

What Alluzience contains

The active substance is botulinum toxin type A*, 200 Speywood units/ml. One vial contains 125 Speywood units in 0.625 ml of solution.
The other ingredients are: L-histidine, Sucrose, Sodium chloride, Polysorbate 80, Hydrochloric acid, Water for injections

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

Botulinum toxin units are not interchangeable from one product to another. Doses recommended in Speywood units are different from other botulinum toxin preparations.

What Alluzience looks like and contents of the packs

Alluzience is a solution for injection. It comes in an individual pack size of 1 or 2 vials or in a multipack comprising 6 individual packs, each containing 2 vials. Not all pack sizes may be marketed. Alluzience is a clear colourless solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[To be completed Nationally]

Manufacturer:
Ipsen Manufacturing Ireland Limited
Blanchardstown Industrial Park
Blanchardstown
Dublin 15
Ireland

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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.

RECOMMENDATIONS FOR THE DISPOSAL OF CONTAMINATED MATERIALS

Immediately after use and prior to disposal, unused Alluzience (which may be present in the vial or in the syringe) should be inactivated with dilute hypochlorite (bleach) solution (1% available chlorine)
Spillage of Alluzience should be wiped up with an absorbent cloth soaked in dilute hypochlorite 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 with dry, absorbent material.
- 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.