Alluzience, 200 Speywood units/ml, solution for injection
- Prescribing Information (Ireland)

Presentation: Each vial contains 125 Speywood units of *Clostridium botulinum* toxin type A haemagglutinin complex in 0.625 ml of solution.
Indications: Alluzience is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at maximum frown in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.
Dosage: Botulinum toxin product units differ depending on the medicinal products. Botulinum toxin units are not interchangeable from one product to another. Doses recommended in Speywood units are different from other botulinum toxin preparations.
Paediatric Population: The safety and efficacy of Alluzience in children aged up to 18 years have not been established. The use of Alluzience is not recommended in patients under 18 years.
Method of administration: Alluzience should only be administered by a physician with appropriate qualifications and expertise in this treatment and having the required equipment. A vial of Alluzience should only be used to treat a single patient, during a single session. Remove any make-up and disinfect the skin with a local antiseptic before administration. The intramuscular injections should be performed using a sterile needle with a suitable gauge. Dosing and treatment intervals depend on assessment of the individual patient's response. The median time to onset as reported subjectively by patients was 3 days (the majority of patients reported an effect within 2 to 3 days with some patients reporting an effect within 24 hours). An effect has been demonstrated for up to 6 months after injection. The treatment interval should be no more frequent than every 3 months.
Administration instructions: The recommended dose is 0.25 ml of solution (50 Speywood units) divided into 5 injection sites, 0.05 ml of solution (10 Speywood units) administered intramuscularly into each of the 5 sites: 2 injections into each *corrugator* muscle and one into the *procerus* muscle, near the nasofrontal angle. The anatomical landmarks can be more readily identified if palpated and observed at patient maximum frown. Before injection, place the thumb or index finger firmly below the orbital rim in order to prevent extravasation below the orbital rim. The needle bevel should be pointed upward and medially during the injection. In order to reduce the risk of ptosis, avoid injections near the *levator palpebrae superioris* muscle, particularly in patients with larger brow-depressor complexes (*depressor supercilii*). Injections should be made into the central part of the *corrugator* muscle, at least 1 cm above the orbital rim.
General information: In the event of treatment failure or diminished effect following repeat injections, alternative treatment methods should be employed. In case of treatment failure after the first treatment session, the following approaches may be considered:
• Analysis of the causes of failure, e.g. incorrect muscles injected, inappropriate injection technique, and formation of toxin-neutralising antibodies
• Re-evaluation of the relevance of treatment with botulinum toxin A.
Contraindications: Hypersensitivity to the active substance or to any of the excipients. Presence of infection at the proposed injection sites. Presence of myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis.
Precautions and Warnings: Care should be taken to ensure that Alluzience is not injected into a blood vessel. Injection of Alluzience is not recommended in patients with a history of dysphagia and aspiration. Adverse reactions possibly related to the spread of toxin effect distant from the site of administration have been reported very rarely with botulinum toxin. Swallowing and breathing difficulties are serious and can result in death. Very rare cases of death, occasionally in the context of dysphagia, pneumopathy (including but not limited to dyspnoea, respiratory failure, respiratory arrest) and/or in patients with significant asthenia have been reported following treatment with botulinum toxin A or B. Patients should be advised to seek immediate medical care if swallowing, speech or respiratory difficulties arise. Alluzience should be used with caution in patients with a risk of, or clinical evidence of, marked defective neuro-muscular transmission. These patients may have an increased sensitivity to agents such as botulinum toxin, and excessive muscle weakness may follow treatment. It is essential to study the patient's facial anatomy prior to administering Alluzience. Facial asymmetry, ptosis, excessive dermatochalasis, scarring and any alterations to this anatomy, as a result of previous surgical interventions, should be taken into consideration. Dry eyes have been reported with use of Alluzience in periocular regions. Attention to this side effect is important since dry eyes may predispose to corneal disorders. Protective drops, ointment, closure of the eye by patching or other means may be required to prevent corneal disorders. The recommended dose and frequency of administration for Alluzience must not be exceeded. Patients treated with the recommended dose may experience exaggerated muscle weakness. Caution should be taken when Alluzience is used in the

presence of inflammation at the proposed injection sites or when the targeted muscle(s) show excessive weakness or atrophy. Cases of muscle atrophy have been reported after the use of botulinum toxin (see 'Undesirable Effects'). As with all intramuscular injections, use of Alluzience is not recommended in patients who have a prolonged bleeding time. Each vial of Alluzience must be used for a single patient treatment during a single session. Any excess of unused product must be disposed of and specific precautions must be taken for the inactivation and disposal of any unused solution.
Antibody formation: Injections at more frequent intervals or at higher doses may increase the risk of neutralising antibody formation to botulinum toxin. Clinically, the formation of neutralising antibodies may reduce the effectiveness of subsequent treatment.
Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
Sodium content: This medicine contains less than 1 mmol sodium (23 mg) per 125U vial, that is to say essentially 'sodium-free'.
Interactions: Concomitant treatment with Alluzience and aminoglycosides or other agents interfering with neuromuscular transmission (e.g. curare-like agents) should only be used with caution since the effect of botulinum toxin may be potentiated. No interaction studies have been performed.
Pregnancy, Breastfeeding and Fertility: *Pregnancy:* There are only limited data from the use of botulinum toxin type A in pregnant women. Animals studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure Alluzience should not be used during pregnancy. *Breastfeeding:* It is unknown if Alluzience is excreted in human milk. Alluzience should not be used during breast-feeding. *Fertility:* There are no clinical data examining the effect of Alluzience on fertility. There is no evidence of direct effect of Alluzience on fertility in animal studies.
Effects on ability to drive and use machines: Alluzience has a minor or moderate influence on the ability to drive and use machines. There is a potential risk of localised muscle weakness or visual disturbances linked with the use of this medicinal product which may temporarily impair the ability to drive or operate machinery.
Undesirable Effects:
A majority of adverse reactions reported with Alluzience in clinical trials were of mild to moderate intensity and reversible. The most frequently reported adverse reactions were headache and injection site reactions. The incidence of adverse reactions tended to decrease with repeated treatments. Adverse effects related to the spread of toxin effect distant from the site of administration have been very rarely reported with botulinum toxin (excessive muscle weakness, dysphagia, aspiration pneumonia with fatal outcomes in some cases). *Adverse Drug Reactions Observed in Clinical Studies* were as follows:
Very common (≥ 1/10): Headache, injection site reactions (periorbital haematoma, haematoma, bruising, pain, paraesthesia erythema, swelling, pruritus, oedema*, rash*, irritation*, discomfort*, stinging*), asthenia*, fatigue*, influenza-like illness*; common (≥ 1/100 to < 1/10): Facial paresis*, eyelid ptosis, eyelid oedema, brow ptosis, dry eye, lacrimation increased, asthenopia*, muscle twitching (twitching of muscles around the eye)*; uncommon (≥ 1/1,000 to <1/100): Dizziness*, eyelid twitching, visual impairment*, vision blurred*, diplopia*, hypersensitivity (eye allergy, hypersensitivity, rash), rash*, pruritus*; rare (≥ 1/10,000 to < 1/1,000): Eye movement disorder*, urticaria*
**additional adverse drug reactions only observed with powder formulation of the same active substance in clinical trials*
Post-marketing experience
Frequency not known: hypoaesthesia, muscle atrophy

Prescribers should consult the summary of product characteristics for further details.
Packaging Quantities and Cost: Pack containing x2 vials: €188.80 excluding VAT
MA Number: PA 1613/004/001
Legal Category: POM
Further information is available from:
Galderma (UK) Ltd, Evergreen House North, Grafton Place, London, NW1 2DX
Telephone: +44 (0)300 3035674
Date of Revision: April 2023

Adverse events should be reported.

Ireland

Suspected adverse events can be reported via HPRA Pharmacovigilance,

Website: www.hpra.ie;

Adverse events should also be reported to Galderma (UK) Ltd:
E-mail: medinfo.uk@galderma.com Tel: +44 (0)300 3035674