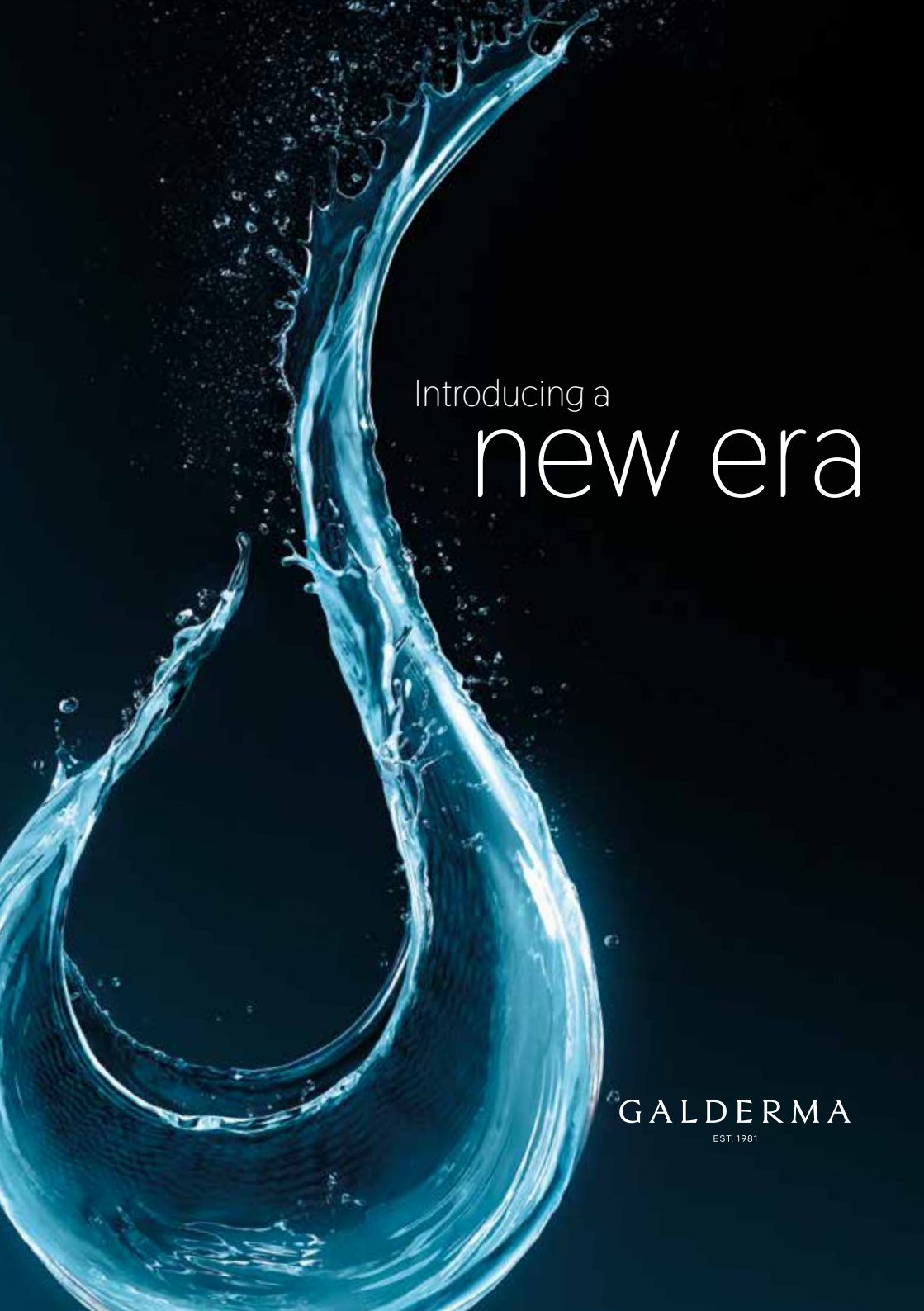

Introducing a
new era
GALDERMA
EST. 1981

Alluzience®

Botulinum toxin type A

THE 1ST READY-TO-USE

BOTULINUM TOXIN TYPE-A IN EUROPE

HELPS DELIVER THE PRECISE DOSE,

MINIMAL MANUAL HANDLING

INNOVATION

An innovative formulation designed to be liquid from inception to injection[1]

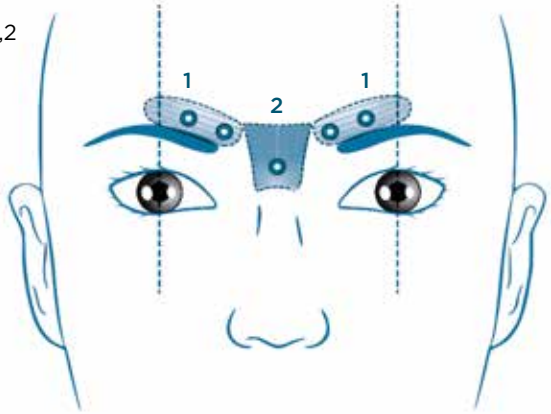
- Ready-to-use and no need to reconstitute
- Pre-diluted to optimised concentration, not freeze-dried
- Free from HAS, animal-derived proteins, and lactose[1]

HAS, Human Albumin Solution.

PRECISION

Recommend dose: 0.25 ML (50 Speywood units) Each of the 5 injection points: 0.05 ML (10 Speywood units)

- Deliver precise results every time[1,2]
- No calculation needed
- Simply draw up and inject



1. Corrugator muscles (2 injections each). 2. Procerus muscle (1 injection).

FOR HEALTHCARE PRACTITIONERS ONLY
Prescribing information can be found at the end of this brochure.
This promotional material has been produced and funded by Galderma

Alluzience is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between eyebrows) seen at a maximum frown in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patients.[1]

PERFORMANCE

ENGINEERED FOR
PRECISION AND PERFORMANCE

Results as soon as **24 hours**[3]

according to self assessment (n=219)

24%

OF PATIENTS

Median time to response: **2 days**[3]

according to self assessment.
Subgroup analysis of responders at day 29 (n=219)

53%

OF PATIENTS

PERFORMANCE
THAT ENDURES

Significant improvement compared to placebo in ILA that lasts up to **6 months** ($p<0.0001$)[4]

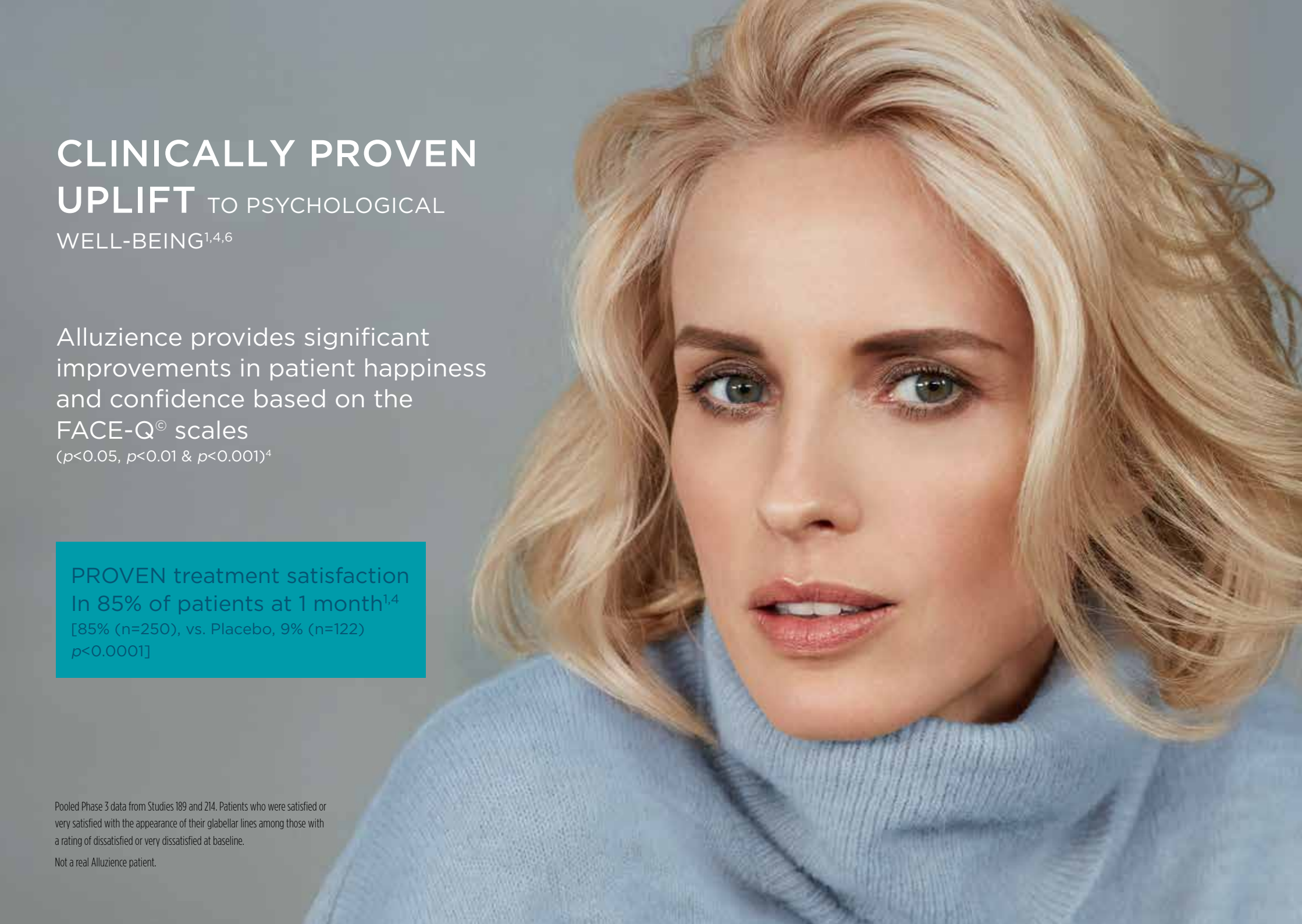
ABO 24% (n=250) vs. placebo 4% (n=122)

Consistent performance over multiple treatment cycles[1,5]

595 patients received up to 5 treatment cycles over 12 months in a long term open-label phase 3 study and by investigator assessment efficacy was maintained over the 12 months.[1]

Data: Post hoc analysis of pooled Phase 3 data from Studies 189 and 214. The efficacy was assessed by pooled outcome of two placebo controlled, randomised clinical trials. The primary endpoint was Investigator Live Assessment (ILA) responder rate at day 29. Alluzience (n=250) ILA day 29: 87.6%. Placebo (n=122) ILA day 29: 2.5%. p<0.0001.
Note 1: Not included in Summary of Product Characteristics.

Note 2: Responders were defined as having glabellar line severity grading of 'none or mild' and calculated based on the modified intention-to-treat population for pooled Studies 189 and 214.
Note 3: Response to onset was defined as 'Yes' in response to 'Since being injected have you noticed an improvement in the appearance of your glabellar lines (lines between your eyebrows)? For the modified intention-to-treat population. Assessed using subject diary cards.
ABO, botulinum toxin type-A ILA, Investigator's Live Assessment.



CLINICALLY PROVEN UPLIFT TO PSYCHOLOGICAL WELL-BEING[1,4,6]

Alluzience provides significant improvements in patient happiness and confidence based on the FACE-Q© scales
(p<0.05, p<0.01 & p<0.001)[4]

PROVEN treatment satisfaction
In 85% of patients at 1 month[1,4]
[85% (n=250), vs. Placebo, 9% (n=122)
p<0.0001]

Pooled Phase 3 data from Studies 189 and 214. Patients who were satisfied or very satisfied with the appearance of their glabellar lines among those with a rating of dissatisfied or very dissatisfied at baseline.

Not a real Alluzience patient.

WELL-TOLERATED

SAFETY PROFILE

A majority of adverse reactions reported with Alluzience in clinical trials were of mild to moderate intensity and reversible[1]

The most frequently reported adverse reactions were headache and injection site reactions[1]

The incidence of adverse reactions tended to decrease with repeated treatments[1]

Contraindications are hypersensitivity to the active substance or to any of the excipients, presence of infection at the proposed injection sites and presence of myasthenia gravis, Easton Lambert syndrome or amyotrophic lateral sclerosis.[1]

The frequency of undesirable effects is classified as follows: Very common (≥ 1/10); common (≥ 1/100 to < 1/10)

Nervous system disorders	Very Common Headache Common Facial paresis*
Eye disorders	Common Eyelid ptosis, eyelid oedema, brow ptosis, dry eye, lacrimation increased, asthenopia*, muscle twitching (twitching of muscles around the eye)*
General disorders and administration site conditions	Very common Injection site reactions (periorbital haematoma, haematoma, bruising, pain, paraesthesia erythema, swelling, pruritus, oedema*, rash*, irritation*, discomfort*, stinging*), asthenia*, fatigue*, influenza-like illness*

*additional adverse drug reactions only observed with powder formulation of the same active substance in clinical trials.

Please refer to the SmPC for the full list of Adverse Drug Reactions.

SmPC, Summary of Product Characteristics.

Alluzience®

Botulinum toxin type A

References:

1. Alluzience SmPC 2022.
2. Galderma. Data on file (MA-43966).
3. Kestemont P, et al. Poster presented at the 19th Aesthetic & Anti-aging Medicine World Congress, Monte Carlo, Monaco, 16-18 September 2021.
4. Kestemont P, et al. Poster presented at the Beauty Through Science meeting, Miami, FL, June 17-19, 2021.
5. Kestemont P, et al. Aesthet Surg J. 2022;42(3):301-313.
6. Ascher B, et al. Aesthet Surg J. 2020;40(9):1000–1008.

Alluzience, 200 Speywood units/ml, solution for injection
– Prescribing Information (United Kingdom)

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 healthcare practitioner with appropriate qualifications and expertise in this treatment and having the required equipment, in accordance with national guidelines. 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. 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. 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*
Prescribers should consult the summary of product characteristics for further details.
Packaging Quantities and Cost: Pack containing x2 vials: £ 160.00 excluding VAT
MA Number: PL 03070/0009
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: June 2022

Adverse events should be reported. For the UK, Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Galderma (UK) Ltd, Email: Medinfo.uk@galderma.com Tel: +44 (0) 300 3035674

Alluzience®

Botulinum toxin type A

A
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by Galderma

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UKI-ALZ-2200012 DOP June 2022