GALDERMA

ADAPTING TO THE AZZALURE BOTULINUM TOXIN TYPE A **VIAL**

WE HAVE MADE SLIGHT CHANGES TO THE DESIGN OF OUR AZZALURE VIAL.

WE HAVE INTRODUCED:

- A firmer stopper, to conform with latest industry standards
- A slightly smaller vial to increase the vacuum.

The volume of the product is unchanged.

WHAT DOES THIS MEAN FOR YOUR DAILY PRACTICE?

If you reconstitute within the vacuum of the vial (ie. keep the stopper in place and push the needle through it) you will not notice any changes.

However, if you remove the stopper before inserting the needle and use a syringe, such as an insulin syringe, then please read on:

Certain types of syringe have a noticeable lip at the joint with the needle.

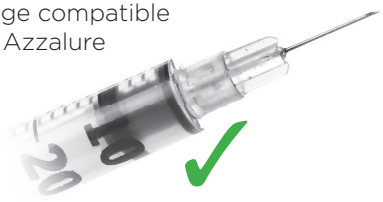
With the Azzalure vial now being around 0.2mm smaller around the neck it is possible that needles on these types of syringe may become stuck or detach in the vial if they are forced in.

HOW TO CHECK YOUR SYRINGE:

The images below highlight the difference in needle/syringe joints.

A Syringe with noticeable lip on needle joint

B Fully integrated syringe compatible with Azzalure



Please note: The recommended needle gauge for Azzalure is 29 or 30G. We also recommend Azzalure is reconstituted according to the instructions contained within the Summary of Product Characteristcs found at www.medicines.org.uk.

Azzalure®
Botulinum toxin type A

Azzalure Abbreviated Prescribing Information (UK & IRE)

Presentation: Botulinum toxin type A (Clostridium botulinum toxin A haemagglutinin complex) 10 Speywood units/0.05ml of reconstituted solution (powder for solution for injection) **Indications:** Temporary improvement in appearance of moderate to severe: • Glabellar lines seen at maximum frown, and/or • lateral canthal lines (crow's feet lines) seen at maximum smile in adult patients under 65 years, when severity of these lines has an important psychological impact on the patient. **Dosage & Administration:** Azzalure should only be administered by physicians with appropriate qualifications and expertise in this treatment and having the required equipment. Botulinum toxin units are different depending on the medicinal products. Speywood units are specific to this preparation and are not interchangeable with other botulinum toxins. Reconstitute prior to injection. Intramuscular injections should be performed using a sterile 29-30 gauge needle. Glabellar lines: recommended dose is 50 Speywood units (0.25 ml of reconstituted solution) divided equally into 5 injection sites, to be administered intramuscularly, at right angles to the skin; 2 injections into each corrugator muscle and one into the procerus muscle near the nasofrontal angle. Lateral canthal lines: recommended dose per side is 30 Speywood units (60 Speywood units for both sides, 0.30 ml of reconstituted solution) divided into 3 injection sites; 10 Speywood units (0.05 ml of reconstituted solution) to be administered intramuscularly into each injection point, .injected lateral (20 - 30° angle) to the skin and very superficial. All injection points should be at the external part of the orbicularis oculi muscle and sufficiently far from the orbital rim (approximately 1 - 2 cm); (See summary of product characteristics for full technique). Treatment interval should not be more frequent than every three months. The efficacy and safety of repeat injections of Azzalure has been evaluated in Glabellar lines up to 24 months and up to 8 repeat treatment cycles and for Lateral Canthal lines up to 12 months and up to 5 repeat treatment cycles. Not recommended for use in individuals under 18 years of age. **Contraindications:** In individuals with hypersensitivity to botulinum toxin A or to any of the excipients. In the presence of infection at the proposed injection sites, myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis. **Special warnings and precautions for use:** Care should be taken to ensure that Azzalure is not injected into a blood vessel. Use with caution in patients with a risk of, or clinical evidence of, marked defective neuro-muscular transmission, in the presence of inflammation at the proposed injection site(s) or when the targeted muscle shows excessive weakness or atrophy. Patients treated with therapeutic doses may experience exaggerated muscle weakness. Not recommended in patients with history of dysphagia, aspiration or with prolonged bleeding time. Seek immediate medical care if swallowing, speech or respiratory difficulties arise. Facial asymmetry, ptosis, excessive dermatochalasis, scarring and any alterations to facial anatomy, as a result of previous surgical interventions should be taken into consideration prior to injection. Injections at more frequent intervals/higher doses can increase the risk of antibody formation. Avoid administering different botulinum neurotoxins during the course of treatment with Azzalure. To be used for one single patient treatment only during a single session. 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. **Interactions:** Concomitant treatment with aminoglycosides or other agents interfering with neuromuscular transmission (e.g. curare-like agents) may potentiate effect of botulinum toxin. **Pregnancy, Lactation & Fertility:** Not to be used during pregnancy or lactation. There are no clinical data from the use of Azzalure on fertility. There is no evidence of direct effect of Azzalure on fertility in animal studies **Side Effects:** Most frequently occurring related reactions are headache and injection site reactions for glabellar lines and; headache, injection site reactions and eyelid oedema for lateral canthal lines.. Generally treatment/injection technique related reactions occur within first week following injection and are transient. Undesirable effects may be related to the active substance, the injection procedure, or a combination of both. For glabellar lines: Very Common (≥ 1/10): Headache, Injection site reactions (e.g. erythema, oedema, irritation, rash, pruritus, paraesthesia, pain, discomfort, stinging and haematoma). Common (≥ 1/100 to < 1/10): Temporary facial paresis (due to temporary paresis of facial muscles proximal to injection sites, predominantly describes brow paresis), Asthenopia, Eyelid ptosis, Eyelid oedema, Lacrimation increase, Dry eye, Muscle twitching (twitching of muscles around the eyes). Uncommon (≥ 1/1,000 to <1/100): Dizziness, Visual impairment, Vision blurred, Diplopia, Pruritus, Rash, Hypersensitivity, Eye movement disorder. Rare (≥ 1/10,000 to < 1/1,000): Urticaria. For lateral canthal lines: Common (≥ 1/100 to < 1/10): Headache, Temporary facial paresis (due to temporary paresis of facial muscles proximal to injection sites), Eyelid ptosis, Eyelid oedema and Injection site disorders (e.g. haematoma, pruritus and oedema). Uncommon (≥ 1/1,000 to <1/100): Dry eye. Adverse reactions resulting from distribution of the effects of the toxin to sites remote from the site of injection have been very rarely reported with botulinum toxin (excessive muscle weakness, dysphagia, aspiration pneumonia with fatal outcome in some cases). Prescribers should consult the summary of product characteristics in relation to other side effects. **Packaging Quantities & Cost:** UK 1 Vial Pack (1 x 125u) £64.00 (RRP), 2 Vial Pack (2 x 125u) £128.00 (RRP), IRE 1 Vial Pack (1 x 125u) €93.50, 2 Vial Pack (2 x 125u) €187.05 (RRP) **Marketing Authorisation Number:** PL 06958/0031 (UK), PA 1609/001/001(IRE) **Legal Category:** POM **Further Information is Available From:** Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts. WD17 1DS, UK. Tel: +44 (0) 1923 208950 Fax: +44 (0) 1923 208998 **Date of Revision:** November 2017

Adverse events should be reported. For the UK, Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
For Ireland, Suspected adverse events can be reported via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
Adverse events should also be reported to Galderma (UK) Ltd.

AZZ17-12-0045 Date of Preparation: Dec 2017

Azzalure®
Botulinum toxin type A