LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Alluzience
(clostridium botulinum neurotoxin type A haemagglutinin complex)

SE/H/2019/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Alluzience
Clostridium botulinum neurotoxin type A haemagglutinin complex

Solution for injection, 200 Speywood units/ml

This is a summary of the public assessment report (PAR) for Alluzience. It explains how Alluzience was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Alluzience.

For practical information about using Alluzience, patients should read the package leaflet or contact their doctor or pharmacist.

What is Alluzience and what is it used for?

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).

How does Alluzience work?

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.

How is Alluzience used?

The pharmaceutical form of Alluzience is solution for injection for intramuscular use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Alluzience have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Alluzience is effective to temporarily improve the appearance of any moderate to severe glabellar lines (the vertical frown lines between the eyebrows).

What are the possible side effects of Alluzience?

For the full list of all side effects reported with Alluzience, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Alluzience approved?

It was noted that the effect of Alluzience to temporarily improve the appearance of any moderate to severe glabellar lines (the vertical frown lines between the eyebrows) was significantly better than treatment with placebo in 2 placebo controlled studies. Therefore, the Medical Products Agency in Sweden decided that Alluzience's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Alluzience?

A risk management plan has been developed to ensure that Alluzience is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Alluzience, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Alluzience

The full PAR for Alluzience can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Alluzience, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-06.