LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Relfydess
(Clostridium botulinum type A neurotoxin)

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Solution for injection, 100 units/ml

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Relfydess and what is it used for?
Relfydess is used to temporarily improve the appearance of moderate to severe vertical lines between the eyebrows (glabellar lines) and moderate to severe lines at the outer corners of your eyes (lateral canthal lines, also known as crow´s feet lines). It is used in adults under 65 years of age in whom those facial lines have an important impact on their well-being.

How does Relfydess work?

Relfydess contains the active substance botulinum toxin A, which causes muscles to relax. It works by inhibiting the nerve impulses to the muscles in which it has been injected to prevent muscles from contracting.

How is Relfydess used?

The pharmaceutical form is solution for injection.

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 Relfydess have been shown in studies?
The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating of:

- *Moderate to severe glabellar lines at maximum frown*
- *Moderate to severe lateral canthal lines seen at maximum smile*

alone or in combination, in adult patients 18 years of age or older, when the severity of these lines has an important psychological impact on the patient.

What are the possible side effects from Relfydess?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Relfydess approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product 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, 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 Relfydess

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

This summary was last updated in 2024-09.