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Ebglyss (*lebrikizumab*)

An overview of Ebglyss and why it is authorised in the EU

What is Ebglyss and what is it used for?

Ebglyss is a medicine used to treat moderate to severe atopic dermatitis (also known as atopic eczema, when the skin is itchy, red and dry). It is used in adults and children aged 12 years and over weighing at least 40 kg. It is used in patients for whom treatment applied directly to the skin cannot be used or is not sufficient.

Ebglyss contains the active substance lebrikizumab.

How is Ebglyss used?

Ebglyss can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of atopic dermatitis. It is available as pre-filled pen or pre-filled syringe.

Ebglyss is given as an injection under the skin, usually in the thigh or belly, every other week for up to 16 weeks. Patients who respond to treatment can then continue treatment with an injection every four weeks. Patients or their carers may inject the medicine themselves if their doctor or nurse considers it appropriate and if they have been trained to do so.

Ebglyss can be used with other treatments for atopic dermatitis applied to the skin (i.e. topical corticosteroids or topical calcineurin inhibitors).

For more information about using Ebglyss, see the package leaflet or contact your healthcare provider.

How does Ebglyss work?

People with atopic dermatitis produce high levels of a protein called interleukin 13 (IL-13), which can cause inflammation of the skin leading to the symptoms of the disease such as itching, dryness and redness. The active substance in Ebglyss, lebrikizumab, is a monoclonal antibody (a type of protein) designed to neutralise IL-13. By doing so, lebrikizumab prevents IL-13 from causing skin inflammation and relieves disease symptoms.

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What benefits of Ebglyss have been shown in studies?

Three main studies have shown that Ebglyss is more effective than placebo (a dummy treatment) at reducing the extent and severity of atopic dermatitis in adults and children above the age of 12 years with moderate to severe disease.

Improvements were measured at 16 weeks using the Investigator's Global Assessment (IGA) scale to rate how severe the condition is (with 0 indicating clear skin and 4 indicating severe disease) and the Eczema Area and Severity Index (EASI) to see how many patients had an improvement of 75% or more in their clinical symptoms across different parts of the body (also known as EASI-75).

In the first study, involving 424 people, 43% of people who received Ebglyss achieved an IGA score of 0 or 1 compared with 13% of people who received placebo. In addition, 59% of people achieved a 75% reduction in their symptom scores (EASI-75) with Ebglyss compared with 16% of people on placebo.

In the second study, involving 445 people, 33% of people had an IGA score of 0 or 1 with Ebglyss compared with 11% of people on placebo. In addition, 52% of people receiving Ebglyss achieved EASI-75 compared with 18% of people receiving placebo.

In the third study, involving 228 people who were also given topical corticosteroids, 41% of people given Ebglyss and corticosteroids had an IGA score of 0 or 1 and 70% achieved EASI-75. The results for people given placebo and corticosteroids were 22% and 42% respectively.

In terms of long-term treatment, the beneficial effect of Ebglyss was maintained up to 52 weeks in people who achieved IGA 0 or 1 and EASI-75 at week 16.

What are the risks associated with Ebglyss?

For the full list of side effects and restrictions with Ebglyss, see the package leaflet.

The most common side effects with Ebglyss (which may affect up to 1 in 10 people) include injection site reactions, dry eye and conjunctivitis (redness and discomfort in the eye) including allergic conjunctivitis.

Why is Ebglyss authorised in the EU?

Ebglyss has been shown to reduce the extent and severity of atopic dermatitis in people with moderate to severe atopic dermatitis, for whom available therapies are limited. Regarding safety, the side effects of Ebglyss usually occur at the start of treatment and are generally mild and manageable.

The European Medicines Agency decided that Ebglyss' benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ebglyss have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ebglyss are continuously monitored. Suspected side effects reported with Ebglyss are carefully evaluated and any necessary action taken to protect patients.

Other information about Ebglyss

Ebglyss received a marketing authorisation valid throughout the EU on 16 November 2023.

Further information on Ebglyss can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ebglyss.

This overview was last updated in 11-2023.