swissmedic

Summary report on authorisation dated 05 August 2025

Ebglyss ® (active substance: lebrikizumab)

Authorisation in Switzerland: 30 August 2024

Medicinal product (pre-filled syringe / pre-filled pen) for the treatment of moderate to severe atopic dermatitis in adults and children aged 12 years and over

About the medicinal product

Ebglyss contains the active substance lebrikizumab and is used to treat adults and children aged 12 years and over weighing at least 40 kg with moderate to severe atopic[1] dermatitis when treatment with medicinal products for external, local application do not provide adequate disease control or are not recommended for medical reasons. Atopic dermatitis is also known as atopic eczema or neurodermatitis.

Atopic dermatitis is a chronic inflammatory disease of the top layers of the skin triggered by various causes and which typically manifests as a red, very itchy rash. Between 5% and up to over 20% of children and up to 10% of all adults are affected by atopic dermatitis.

Most cases involve mild forms that can be well controlled with medicinal products applied locally to the skin, such as skin ointments. However, there are more severe forms of atopic dermatitis that may require additional treatments.

The medicinal product Ebglyss can help alleviate the symptoms of atopic dermatitis and reduce the itching.

Mode of action

The active substance in Ebglyss, lebrikizumab, is what is known as a monoclonal antibody. Lebrikizumab recognises and binds to certain proteins in the body. One feature of atopic dermatitis is an increase in the concentration of the protein interleukin-13 (IL-13) in the body. This protein plays a crucial role in the development of atopic dermatitis. Lebrikizumab binds to interleukin-13, disrupting a chain of signals that

[1] Atopy: Atopy refers to an allergic hypersensitivity to otherwise harmless natural and synthetic substances in the environment.

normally cause the skin inflammation and itching in atopic dermatitis.

This mechanism of action enables the medicinal product Ebglyss containing the active substance lebrikizumab to alleviate the symptoms of atopic dermatitis.

Administration

Ebglyss is a prescription-only medicine and is available as a pre-filled syringe and pre-filled pen containing 250 mg of the active substance lebrikizumab. Ebglyss is administered under the skin, preferably in the thigh or stomach.

Treatment is initiated by a medical professional with experience in the diagnosis and treatment of atopic dermatitis.

The recommended starting dose is 500 mg (two 250-mg injections) at the start of treatment and in the second subsequent week. After that, one 250-mg injection is administered every two weeks.

After 16 weeks, the doctor will decide on the basis of clinical response whether further treatment with Ebglyss at a maintenance dose of one injection (250 mg) every four weeks is worthwhile.

Patients can inject the medicinal product Ebglyss themselves or have it administered by a suitably trained carer if their doctor feels this is appropriate.

Ebglyss can be used in combination with medicinal products for application to the skin or on its own.

Efficacy

The efficacy of Ebglyss in treating atopic dermatitis was investigated in three clinical studies involving a total of 1,062 participants with moderate to severe disease.

The severity of atopic dermatitis is determined by scores achieved on rating scales (e.g. IGA or EASI). The corresponding improvements in the scores were also used to confirm the effect in the clinical studies.

Participants in the ADvocate-1 and ADvocate-2 trials received either lebrikizumab or a dummy drug (placebo) for a period of 16 weeks. Patients received lebrikizumab or placebo for a further 36 weeks to assess whether response was maintained. The trials lasted 52 weeks.

The trials demonstrated that participants treated with lebrikizumab showed a clearer improvement in scores after 16 weeks than participants in the placebo group. Even after 52 weeks, significantly more trial participants had been able to maintain their response to lebrikizumab compared with the placebo group.

The ADhere study compared a combination of lebrikizumab and locally applied medicines with a combination of placebo and medicinal products applied to the skin. Like the ADvocate studies, this study showed better scores compared with the placebo group.

This results of the study show that the medicinal product Ebglyss containing the active substance lebrikizumab is effective both on its own and in combination with medicinal products applied to the skin and is capable of alleviating the symptoms associated with atopic dermatitis.

Precautions, undesirable effects, & risks

Ebglyss must not be used in those who are hypersensitive to the active substance or any of the excipients.

The commonest undesirable effects are conjunctivitis, redness and itching of the eyes, injection site reactions and dry eyes.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Atopic dermatitis is a chronic skin condition that causes severe itching and affects a large number of patients worldwide. It can significantly impair quality of life and often requires treatment to alleviate symptoms and avoid exacerbation.

The completed studies showed a benefit for Ebglyss, compared to placebo, in the treatment of atopic dermatitis in adolescents and adults with moderate to severe atopic dermatitis that cannot be controlled by local, topical treatment (e.g. skin ointments).

Taking all the risks and precautions into account, and based on the available data, the benefits of Ebglyss outweigh the risks. Swissmedic has therefore authorised the medicinal product Ebglyss containing the active substance lebrikizumab in Switzerland for the treatment of moderate to severe atopic dermatitis in adults and children aged 12 years and over.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ebglyss®

Information for patients (package leaflet): Patient information Ebglyss®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.
Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.