



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2023
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Ebglyss lebrikizumab

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ebglyss, intended for the treatment of atopic dermatitis. The applicant for this medicinal product is Almirall, S.A.

Ebglyss will be available as a 250 mg solution for injection. The active substance of Ebglyss is lebrikizumab, a recombinant human IgG4 monoclonal antibody (ATC code: not yet assigned). It works by inhibiting interleukin-13 signalling, which has an important role in skin inflammation, infections and pruritus that characterize atopic dermatitis.

The benefit of Ebglyss is its ability to improve disease symptoms as measured by the Investigator's Global Assessment (IGA) and Eczema Area and Severity Index (EASI)-75 scale in patients with atopic dermatitis. The most common side effects are conjunctivitis, injection site reactions, allergic conjunctivitis and dry eye.

The full indication is:

Ebglyss is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy.

Ebglyss should be initiated by healthcare professionals experienced in the diagnosis and treatment of atopic dermatitis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

