24 July 2025
EMA/CHMP/172918/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ekterly

sebetralstat

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ekterly[2], intended for the symptomatic treatment of acute attacks of hereditary angioedema in adults and adolescents from 12 years of age. The applicant for this medicinal product is KalVista Pharmaceuticals (Ireland) Ltd.

Ekterly will be available as 300 mg film-coated tablets. The active substance of Ekterly is sebetralstat, a drug used in hereditary angioedema (ATC code: B06AC08). Sebetralstat is an inhibitor of plasma kallikrein. Sebetralstat also suppresses the activation of the positive feedback mechanism of the kallikrein-kinin system, thereby reducing factor XIIa and additional plasma kallikrein production. By inhibiting plasma kallikrein, sebetralstat reduces the production of bradykinin, thereby halting the progression of hereditary angioedema attacks. This is the first oral treatment for hereditary angioedema.

The benefit of Ekterly is a shorter time to the beginning of symptom relief in adults and adolescents with acute attacks of hereditary angioedema compared with placebo, as shown in a randomised, double-blind, placebo-controlled, three-way crossover phase 3 study. The most common side effect with Ekterly is headache.

The full indication is:

> Ekterly is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older.

Ekterly should be initiated by a healthcare professional experienced in the management of patients with hereditary angioedema.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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