swissmedic

Summary report on authorisation dated 13 February 2026

Ekterly® (active substance: sebetralstat)

Authorisation in Switzerland: 17 September 2025

Film-coated tablets for the treatment of acute attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older

About the medicinal product

Ekterly contains the active substance sebetralstat. The medicinal product Ekterly is used for the treatment of acute attacks of the disease hereditary[1] angioedema (HAE) in adult and adolescent patients aged 12 years and over.

HAE is a rare inherited disease that causes episodic, painful swellings in various parts of the body, such as the face, hands, arms, legs and feet, or the gastrointestinal tract. The swellings can be life-threatening if they occur in the upper respiratory tract.

The swellings associated with HAE are triggered by an overactivity of the enzyme plasma kallikrein and the consequent production and release of excessive amounts of the messenger substance bradykinin. Bradykinin causes dilation of the blood vessels, which allows fluid to leak into the surrounding tissue, resulting in the typical swellings and inflammation. The active substance sebetralstat blocks the activity of plasma kallikrein and thus the increased formation of bradykinin in the affected patients. As a result of this mechanism of action, vascular permeability is reduced and the medicinal product Ekterly is able to halt the progression of HAE attacks.

Since HAE is a rare and life-threatening disease, Ekterly has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

The medicinal product Ekterly was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic. The joint initiative coordinates the assessment of applications for authorisation and variation that have been submitted in at least two of the five countries.

The authorisation application for Ekterly was submitted for assessment to the regulatory authorities in Australia, Singapore, the

[1] Hereditary means "inherited"

United Kingdom and Switzerland. The results of the assessment were shared and discussed with the participating regulatory authorities. At the end of the process, each authority decided on the application independently. Swissmedic took the assessment of the foreign reference authorities into account when deciding whether to authorise Ekterly.

The requirements for issuing a comprehensive SwissPAR (Swiss Public Assessment Report) and a Summary report on authorisation based on this SwissPAR have not been fulfilled. Swissmedic refers to the authorisation of the foreign reference authorities.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch)

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ekterly®

Information for patients (package leaflet): Information for patients Ekterly®
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.