EKTERLY® (SEBETRALSTAT)
RISK MANAGEMENT PLAN
Summary

RMP Version Number:	1.2
Document Date:	03 November 2025
Based on EU RMP version number:	1.2 (signed 12 June 2025)
Marketing Authorisation holder:	KalVista Pharmaceuticals Switzerland GmbH Baarestrasse 135, 6300 Zug Switzerland

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP Summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of "Bezeichnung des Arzneimittels" is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of "Bezeichnung des Arzneimittels" in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Name of the marketing authorisation holder" is fully responsible for the accuracy and correctness of the content of the published summary RMP of "Bezeichnung des Arzneimittels".

Summary of the risk management plan for Ekterly (sebetralstat)

This is a summary of the risk management plan (RMP) for Ekterly (sebetralstat). The RMP details important risks of Ekterly, how these risks can be minimised, and how more information will be obtained about Ekterly's risks and uncertainties (missing information).

Ekterly's summary of product characteristics (SmPC) and its package leaflet give healthcare professionals and patients essential information on how Ekterly should be used.

This summary of the RMP for Ekterly should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Ekterly's RMP.

I. The medicine and what it is used for

Ekterly is authorised for the symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older (see SmPC for the full indication). It contains sebetralstat as the active substance, and it is given orally.

Further information about the evaluation of Ekterly's benefits can be found in Ekterly's EPAR, including in its plain-language summary, available on the EMA website under the medicine's webpage European Public Assessment Reports (EPARs).

II. Risks associated with Ekterly and activities to minimise or further characterise the risks

Important risks of Ekterly, together with measures to minimise such risks and the proposed studies for learning more about Ekterly's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Ekterly is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ekterly are risks that need special risk management activities to investigate further or minimise the risk so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Ekterly. Potential risks are concerns for which an association with this medicine is possible based on available data, but this association has not been established yet and needs further evaluation.

Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

There are no important identified risks, important potential risks, or missing information that are considered important for inclusion in the list of safety concerns in the Ekterly RMP.

II.C Post-Authorisation Development Plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Ekterly.

II.C.2 Other studies in the post-authorisation development plan

There are no studies required for Ekterly.