Ebglyss®

Lebrikizumab

250 mg solution for injection in pre-filled syringe
250 mg solution for injection in pre-filled pen

Summary of Risk Management Plan (RMP)

Document version: 1.0
Marketing Authorization Holder: Almirall, AG
Document Date: 11.10.2024
Based on EU-RMP version 1.0 (27.09.2023)

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 Ebglyss® 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 Ebglyss® in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

Almirall AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Ebglyss®.

Part VI: Summary of the risk management plan

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

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

This summary of the RMP for Ebglyss should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all 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 Ebglyss’s RMP.

I. The medicine and what it is used for

Ebglyss is authorised for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years of age and older with a body weight of at least 40 kg who are candidates for systemic therapy (see SmPC for the full indication). It contains lebrikizumab as the active substance and it is given by subcutaneous injection.

Further information about the evaluation of Ebglyss’s benefits can be found in Ebglyss’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage.

II. Risks associated with the medicine and activities to minimise or further characterize the risks

Important risks of Ebglyss, together with measures to minimise such risks and the proposed studies for learning more about Ebglyss ‘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 so 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 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 Ebglyss is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Ebglyss are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Ebglyss. Potential risks are concerns for which an association with the use of 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	Use in pregnant and breastfeeding women Long-term safety of lebrikizumab

II.B. Summary of important risks

Missing information: Use in pregnant and breastfeeding women	
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.6 recommends avoiding the use of lebrikizumab in pregnancy. The use during lactation should be evaluated taking into account the potential benefit-risk. PL Section 2, Pregnancy, breast-feeding and fertility recommends that it is preferable to avoid the use of Ebglyss in pregnancy and lactation unless your doctor advises to use it. Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities (Pregnant Women): Observational database study of pregnancy and infant outcomes among women exposed to lebrikizumab during pregnancy See section II.C of this summary for an overview of the post-authorisation development plan.

Missing information: Long-term safety of lebrikizumab	
Risk minimisation measures	Routine risk minimisation measures: None Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: • A long-term study to assess the safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis (J2T-DM-KGAA) • Long-term safety and efficacy of lebrikizumab in adult and adolescent patients with moderate-to-severe atopic dermatitis (M-17923-32) See section II.C of this summary for an overview of the post-authorisation development plan.

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Ebglyss.

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

Study Short Name: Observational Database Study of Pregnancy and Infant Outcomes Among Women Exposed to Lebrikizumab During Pregnancy

Purpose of the study:

To estimate the occurrence of certain adverse pregnancy and infant outcomes among women exposed to lebrikizumab in pregnancy. If the sample size permits, the study aims to estimate the relative risk of the adverse pregnancy and infant outcomes among women with AD exposed to lebrikizumab in pregnancy compared to women with AD unexposed to lebrikizumab in pregnancy.

Study Short Name: A long-term study to assess the safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis (J2T-DM-KGAA)

Purpose of the study:

To evaluate the long-term safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis up to 100 weeks.

Study Short Name: Long-term safety and efficacy of lebrikizumab in adult and adolescent patients with moderate-to-severe atopic dermatitis (M-17923-32)

Purpose of the study:

To evaluate the long-term safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis for up to 2 additional years.