Swiss Summary of the Risk Management Plan (RMP) for

Exdensur

(Depemokimab)

RMP Summary:	Version 1.0
Document date:	02.11.2026
EU RMP:	Version 1.0, February 2026
License holder:	GlaxoSmithKline AG, Baar

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 minimize them.

The RMP summary of Exdensur 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 Exdensur in Switzerland is the „Arzneimittelinformation/Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

GlaxoSmithKline AG is fully responsible for the accuracy and correctness of the content of the published summary RMP for Exdensur.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Exdensur (Depemokimab)

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

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

This summary of the RMP for Exdensur 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 Exdensur's RMP.

I. The medicine and what it is used for

Exdensur is authorized for asthma and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (see SmPC for the full indication). It contains depemokimab as the active substance and it is given by subcutaneous route.

See SmPC for further indication information, dose and method of administration.

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

https://www.ema.europa.eu/en/medicines/human/EPAR/exdensur

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

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

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed. These measures constitute routine pharmacovigilance activities.

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

II.A List of important risks and missing information

Important risks of Exdensur are risks that need special risk management activities to further investigate or minimize 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 Exdensur. 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 patients

II.B Summary of important risks

Missing information	
Risk minimization measures	**Routine risk minimization measures:** The SmPC Section 4.6, Fertility, Pregnancy and Lactation, of the SmPC advises prescribers on the non-clinical reproductive toxicity data available relating to Exdensur which states that there are no or limited amount of data from the use of depemokimab in pregnant women. **Additional risk minimization measures:** None

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of Exdensur.

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

There are no studies required for Exdensur.