



Swiss Summary of the Risk Management Plan (RMP) for

**XEVUDY
(Sotrovimab)**

RMP Summary: Version 2, May 2024
EU RMP: Version 1.1, 07 March 2024

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 Xevudy 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 Xevudy 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 of Xevudy.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Xevudy (Sotrovimab)

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

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

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

I. The medicine and what it is used for

Xevudy is authorized for the treatment of patients with coronavirus disease 2019 (COVID-19) who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID-19 (see SmPC for the full indication). It contains sotrovimab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of Xevudy's benefits can be found in Xevudy'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/xevudy>

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

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

II.A List of important risks and missing information

Important risks of Xevudy 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 Xevudy. 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	
Missing information	Use in pregnancy

II.B Summary of important risks

Missing Information: Use in pregnancy	
Risk minimization measures	<p>Routine risk minimization measures:</p> <p>The SmPC includes appropriate information in Section 4.6, Fertility, Pregnancy and Lactation, and Section 5.3 Preclinical Safety Data</p> <p>Equivalent wording is included in the patient leaflet Section 2</p> <p>Additional risk minimization measures:</p> <p>None</p>

Additional pharmacovigilance activities	Additional pharmacovigilance activities: <i>Short study name:</i> COVID-19 International Drug Pregnancy Registry (COVID-PR) <i>See section II.C of this summary for an overview of the post- authorization development plan.</i>
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II.C Post-authorisation development plan

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

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

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

Study Short Name:

COVID-19 International Drug Pregnancy Registry (COVID-PR)

Purpose of the Study:

The overall objective of the COVID-19 International Multi-Drug Pregnancy Registry (COVID-PR) is to evaluate obstetric, neonatal, and infant outcomes among women who required at least one in-hospital or ambulatory medication for mild to severe COVID-19 at any time during pregnancy. Sotrovimab exposure in pregnancy is one of the medications monitored in the COVID-PR.