Swiss Public Summary of the Risk Management Plan (RMP)

for

Sunlenca®, solution for injection
Sunlenca®, film-coated tablets

(Lenacapavir)

Version 2.0 (May 2024)
Based on EU RMP version 2.0 (February 2024)

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SUMMARY OF RISK MANAGEMENT PLAN FOR SUNLENCA® (LENACAPAVIR)

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 Sunlenca 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 Sunlenca in Switzerland is the „Arzneimittelinformation / Information sur le médicament“ (see www.swissmedic.ch) approved by Swissmedic. Gilead Sciences Switzerland Sàrl is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Sunlenca.

SUMMARY OF RISK MANAGEMENT PLAN FOR LENACAPAVIR

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

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

This summary of the RMP for LEN 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 the LEN RMP.

I. The Medicine and What Is It Used For

Lenacapavir, in combination with other antiretroviral(s), is indicated for the treatment of adults with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. It contains LEN as the active substance, and it is given as both an oral tablet and a subcutaneous (SC) injection.

Further information about the evaluation of LEN's benefits can be found in the LEN EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/sunlenca

II. Risks Associated With the Medicine and Activities to Minimize or Further Characterize the Risks

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

II.A. List of Important Risks and Missing Information

Important risks 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 a medicinal product. 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);

Table Part VI.1. List of Important Risks and Missing Information

Important Identified Risks	None
Important Potential Risks	None
Missing Information	Long-term safety
	Safety in pregnancy and lactation

II.B. Summary of Important Risks

Lenacapavir has been assigned the legal status of a medicine subject to medical prescription in the European Union (EU), whereby therapy should be initiated by a doctor experienced in the management of HIV-1 infection (as described in section 4.2 of the SmPC).

Table Part VI.2. Summary of Important Risk(s) and Missing Information

Important Identified Risks	**None**
Important Potential Risk	**None**
Missing information	**Long-term safety**
Risk Minimization Measure(s)	Other routine risk minimization measures beyond the Product Information: Medicine's legal status: restricted medical prescription, whereby therapy should be initiated by a physician experienced in the management of HIV-1 infection
Additional Pharmacovigilance activities	Additional pharmacovigilance activities: • **Study GS-US-200-4625** - Safety of LEN in Heavily-Treatment-Experienced (HTE) participants with multi drug resistant HIV-1 infection

	• **Study GS-US-200-4334** - Safety of LEN in treatment-naive participants with HIV-1 infection See Section II.C of this summary for an overview of the post-authorization development plan.
Missing information	**Safety in pregnancy and lactation**
Risk Minimization Measure(s)	Routine risk communication: SmPC section 4.6 PL section 2 Other routine risk minimization measures beyond the Product Information: Medicine's legal status: restricted medical prescription, whereby therapy should be initiated by a physician experienced in the management of HIV-1 infection
Additional Pharmacovigilance activities	Additional pharmacovigilance activities: • **Antiretroviral Pregnancy Registry (APR)** See Section II.C of this summary for an overview of the post-authorization development plan.

II.C. Postauthorization 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 LEN.

II.C.2. Other Studies in Postauthorization Development Plan

Table Part VI.3. Other Studies in Postauthorization Development Plan

Short Study Name	Purpose of the Study
Study GS-US-200-4625 - Safety of LEN in HTE participants with multi drug resistant HIV-1 infection	To evaluate the safety of LEN in combination with an optimized background regimen (OBR) through 52 weeks of treatment in adults with MDR HIV-1 who are failing their current regimen.
Study GS-US-200-4334 - Safety of LEN in treatment-naive participants with HIV-1 infection	To evaluate the safety of LEN-containing regimens through 80 weeks of treatment in treatment-naïve participants with HIV-1.
Antiretroviral Pregnancy Registry (APR)	To collect information on the risk of birth defects with antiretroviral drugs, including LEN, to which pregnant women are exposed.