Swiss Summary of the Risk Management Plan (RMP)

for

Veklury®, Powder for concentrate for solution for infusion

(Remdesivir)

Version 4.0 (October 2023)
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SUMMARY OF RISK MANAGEMENT PLAN FOR VEKLURY® (REMDESIVIR)

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 Veklury 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 Veklury in Switzerland is the „Arzneimittelinformation / Information sur le médicament“ (see www.swissmedic.ch) approved and temporarily authorized by Swissmedic. Veklury has received temporary authorisation by Swissmedic.

Gilead Sciences Switzerland Sàrl is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Veklury.

I. The Medicine and What is it Used for

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in:

- adults and pediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment).

- adults and pediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19 (see SmPC for the full indication).

It contains remdesivir as the active substance and it is given by intravenous infusion.

Further information about the evaluation of Veklury’s benefits can be found in Veklury’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/veklury.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterize the Risks

Important risks of Veklury, together with measures to minimise such risks and the proposed studies for learning more about Veklury’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 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 minimise its risks.

Together, these measures constitute routine risk minimization 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 Veklury 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 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 Veklury. 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	Safety in patients with hepatic impairment
	Safety in pregnant and lactating women

II.B. Summary of Important Risks and Missing Information

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

Missing information	**Safety in patients with hepatic impairment**
Risk Minimization Measure(s)	Routine risk minimization measures: SmPC section 4.2, 4.4, 4.8 and 5.2 PL section 2
Additional Pharmacovigilance activities	Additional pharmacovigilance activities: Study GS-US-540-9014 (Phase 1 study in subjects with hepatic impairment) See Section II.C.2 of this summary for an overview of the post-authorisation development plan.
Missing information	**Safety in pregnant and lactating women**
Risk Minimization Measure(s)	Routine risk minimization measures: SmPC section 4.6 PL section 2
Additional Pharmacovigilance activities	Additional pharmacovigilance activities: Remdesivir pregnancy safety report Study of the pharmacokinetics (PK) and safety of RDV in pregnant women (IMPAACT 2032) See Section II.C.2 of this summary for an overview of the post-authorisation development plan.

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 obligations for Veklury.

II.C.2. Other Studies in Post-Authorization Development Plan

Table Part VI.3. Other Studies in Post-Authorization Development Plan

Program Name	Purpose of the Program
Remdesivir pregnancy safety report	*Safety concern addressed:* Safety in pregnancy (missing information) O*bjectives:* To provide information on pregnant women and birth outcomes with the use of remdesivir during pregnancy from postmarketing sources and the compassionate use program (IN-US-540-5755) and expanded access program (GS-US-540-5821).
Study GS-US-540-9014 Phase 1 study in subjects with hepatic impairment	*Safety concern addressed:* Safety in patients with hepatic impairment (missing information) *Objectives:* To evaluate the pharmacokinetics of remdesivir and its metabolite(s) in subjects with hepatic impairment.
Study of the PK and safety of RDV in pregnant women (IMPAACT 2032)	*Safety concern addressed:* Safety in pregnancy (missing information) *Objectives:* To evaluate the pharmacokinetics and safety of remdesivir in pregnant individuals with coronavirus disease 2019 (COVID-19).

This summary was last updated in 10-2023.