Swiss Public Summary of the Risk Management Plan (RMP)

for

Stribild®, film-coated tablets

(Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Disoproxil Fumarate)

Version 1.0 (March 2023)
Based on EU RMP version 15.0 (December 2022)

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

SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR STRIBILD

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

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

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

I. The Medicine and What It Is Used for

Stribild is authorized for the treatment of adults infected with human immunodeficiency virus-1 (HIV-1) (see SmPC for the full indication). Stribild is also used to treat HIV-1 infected adolescents aged 12 to < 18 years who weigh at least 35 kg, and who have already been treated with other HIV medicines that have caused side effects. It contains elvitegravir (EVG), cobicistat (COBI) emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF) as the active substances and it is given orally.

Further information about the evaluation of Stribild's benefits can be found in Stribild's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/002574/WC500144275.pdf.

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

Important risks of Stribild, together with measures to minimize such risks and the proposed studies for learning more about Stribild'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 the case of Stribild, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

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 Stribild is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Stribild 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 Stribild. 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 pregnancy and lactation

II.B. Summary of Important Risks

There are no important identified or potential risks for Stribild. STB has been assigned the legal status of a medicine subject to medical prescription in the European Union (EU), whereby STB therapy should be initiated by a doctor experienced in the management of HIV infection (as described in section 4.2 of the SmPC).

Table Part VI.2. Summary of Missing Information

Missing Information	Safety in Pregnancy and Lactation
Risk Minimization Measure(s)	Routine risk communication: SmPC Section 4.6 PL Section 2
Additional Pharmacovigilance activities	Antiretroviral Pregnancy Registry See Section II.C of this summary for an overview of the post-authorization 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 obligation of Stribild.

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

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

Short Study Name	Purpose of the Study
Antiretroviral Pregnancy Registry	To collect information on the risk of birth defects in patients exposed to anti-HIV medicines, including the components of Stribild, during pregnancy