Summary of risk management plan for Emtricitabin-Tenofovir-Mepha® (Emtricitabin-Tenofovir Disoproxil)

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Disclaimer

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 risk as well as to prevent or minimize them.

The RMP summary of Emtricitabin-Tenofovir-Mepha ® 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 Emtricitabin-Tenofovir-Mepha ® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Mepha Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Emtricitabin-Tenofovir-Mepha ®.

Summary of Risk Management Plan for EMTRICITABINE/TENOFOVIR DISOPROXIL 200mg/245mg Film-coated tablets

This is a summary of the risk management plan (RMP) for EMTRICITABINE/TENOFOVIR DISOPROXIL 200mg/245mg Film-coated tablets, (hereinafter referred to as Emtricitabine/tenofovir disoproxil). The RMP details important risks of Emtricitabine/tenofovir disoproxil, how these risks can be minimised, and how more information will be obtained about Emtricitabine/tenofovir disoproxil's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Emtricitabine/tenofovir disoproxil's RMP.

I. The Medicine and What It is used for

Emtricitabine/tenofovir disoproxil is authorised for the treatment of HIV-1 infected adults and certain adolescents, as well as for pre-exposure HIV prophylaxis (see SmPC for the full indication). It contains emtricitabine and tenofovir disoproxil as the active substances and it is given orally.

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

Important risks of Emtricitabine/tenofovir disoproxil, together with measures to minimise such risks and the proposed studies for learning more about Emtricitabine/tenofovir disoproxil'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 authorised 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Emtricitabine/tenofovir disoproxil, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, 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 emtricitabine/tenofovir is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of Emtricitabine/tenofovir disoproxil are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Emtricitabine/tenofovir disoproxil. 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 1: Summary of Safety Concerns

Summary of safety concerns	
Important identified risks	• HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) • Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)
Important potential risks	• None
Missing information	• Safety in pregnancy and lactation

II.B Summary of Important Risks

Table 2: Summary of Risk Minimisation Activities by Safety Concern

Important identified risks (PrEP indication): **HIV-1 acquisition, including infection resulting from non-adherence** **Development of resistance in patients with unrecognized or acute HIV-1 infection**	
Risk minimisation measures	Routine risk minimisation measures Statement warning in SmPC section 4.3. Statements in SmPC section 4.4. Recommendations on HIV testing at frequent intervals while taking emtricitabine/tenofovir for pre-exposure prophylaxis in SmPC section 4.4. Risk is described in PL sections 2 and 3. Legal status: Prescription only medicine. Additional risk minimisation measures Specific PrEP educational materials.

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 authorisation or specific obligation of Emtricitabine/tenofovir disoproxil.

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

There are no studies required for Emtricitabine/tenofovir disoproxil.