Part VI: Summary of the Risk Management Plan

Summary of risk management plan (RMP) for emtricitabine/tenofovir disoproxil Glenmark (emtricitabine/tenofovir disoproxil)

This is a summary of the RMP for emtricitabine/tenofovir disoproxil Glenmark. The RMP details important risks of emtricitabine/tenofovir disoproxil Glenmark, how these risks can be minimised, and how more information will be obtained about emtricitabine/tenofovir disoproxil Glenmark risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Emtricitabine/tenofovir disoproxil Glenmark is authorised in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) type 1 infected adults. It is also indicated for the treatment of HIV-1 infected adolescents, with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line agents.

Emtricitabine/tenofovir disoproxil Glenmark is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents at high risk.

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 Glenmark, together with measures to minimise such risks and the proposed studies for learning more about emtricitabine/tenofovir disoproxil Glenmark 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 HCPs;
- 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 Glenmark, 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 disoproxil Glenmark 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 Glenmark 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 Glenmark. 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	
Important identified risk(s)	• HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) (Emtricitabine/Tenofovir disoproxil) • Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication) (Emtricitabine/Tenofovir disoproxil) • Renal toxicity (Tenofovir disoproxil) • Bone events due to proximal renal tubulopathy/loss of bone mineral density (Tenofovir disoproxil)
Important potential risk(s)	• None
Missing information	• Safety in pregnancy and lactation (Tenofovir disoproxil)

II.B. Summary of important risk

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important Identified Risk – HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) (Emtricitabine/Tenofovir disoproxil)	
Risk minimisation measures	Routine risk minimisation measures: **SmPC** • Section 4.4: Special warnings and precautions for use **Patient Information Leaflet (PIL):** Section 2: What you need to know before you take Product name

Important Identified Risk – HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) (Emtricitabine/Tenofovir disoproxil)	
	Additional risk minimisation measures: Education program for prescribers and individuals at risk, which includes: • PrEP educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card for the individual at risk

Important Identified Risk – Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication) (Emtricitabine/Tenofovir disoproxil)	
Risk minimisation measures	Routine risk minimisation measures: **SmPC** • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use **PIL:** • Section 2: What you need to know before you take Product name Additional risk minimisation measures: Education program for prescribers and individuals at risk, which includes: • PrEP educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card for the individual at risk

Important Identified Risk – Renal toxicity (Tenofovir disoproxil)	
Risk minimisation measures	Routine risk minimisation measures: **SmPC** • Section 4.2: Posology and method of administration • Section 4.4: Special warnings and precautions for use • Section 4.5: Interaction with other medicinal products and other forms of interaction • Section 4.8: Undesirable effects

Important Identified Risk – Renal toxicity (Tenofovir disoproxil)	
	PIL: • Section 2: What you need to know before you take Product name • Section 4: Possible side effects <u>Additional risk minimisation measures:</u> • **HIV-1 indication:** HIV educational guide for prescribers to paediatric patients • **PrEP indication:** PrEP indication educational guide for prescribers

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 Glenmark.

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

There are no studies required for emtricitabine/tenofovir disoproxil Glenmark.