Summary of risk management plan for Emtricitabine/Tenofovir disoproxil Krka d.d.

This is a summary of the risk management plan (RMP) for Emtricitabine/Tenofovir disoproxil Krka d.d.. The RMP details important risks of Emtricitabine/Tenofovir disoproxil Krka d.d., how these risks can be minimised, and how more information will be obtained about Emtricitabine/Tenofovir disoproxil Krka d.d.'s risks and uncertainties (missing information).

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

This summary of the RMP for Emtricitabine/Tenofovir disoproxil Krka d.d. 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 Emtricitabine/Tenofovir disoproxil Krka d.d.'s RMP.

I. The medicine and what it is used for

Emtricitabine/Tenofovir disoproxil Krka d.d. is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults, for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years and indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.

It contains Emtricitabine/Tenofovir disoproxil as the active substance and it is given orally.

Further information about the evaluation Emtricitabine/Tenofovir disoproxil Krka d.d.’s benefits can be found in Emtricitabine/Tenofovir disoproxil Krka d.d.’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/emtricitabinetenofovir-disoproxil-krka-dd

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Emtricitabine/Tenofovir disoproxil Krka d.d., together with measures to minimise such risks and the proposed studies for learning more about Emtricitabine/Tenofovir disoproxil Krka d.d.'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 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 Krka d.d.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 Krka d.d. 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 Krka d.d.. 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);

Summary of safety concerns	
Important identified risks:	None
Important potential risks:	None
Missing information:	Safety in pregnancy and lactation (tenofovir)

II.B Summary of important risks

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

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 Krka d.d.

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

There are no studies required for Emtricitabine/Tenofovir disoproxil Krka d.d.