Summary of risk management plan for Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten:

This is a summary of the risk management plan (RMP) for Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten. The RMP details important risks of Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten, how these risks can be minimised, and how more information will be obtained about Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten's risks and uncertainties (missing information).

Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten should be used.

Important new concerns or changes to the current ones will be included in updates of Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten's RMP.

I. The medicine and what it is used for

Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten are authorised for (See SmPC for the full indication):

Treatment of human immunodeficiency virus (HIV)-1 infection:

- antiretroviral combination therapy for the treatment of HIV-1 infected adults.
- treatment of HIV-1 infected adolescents, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents.

Pre-exposure prophylaxis (PrEP):

- in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents at high risk

Emtricitabin/Tenofovir disoproxil Tillomed 200 mg/245 mg Filmtabletten contain Emtricitabine and Tenofovir disoproxil as the active substance and are given by oral route.

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

Important risks of Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten, together with measures to minimise such risks and the proposed studies for learning more about Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten'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 PL 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 Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten, 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 Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten 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 Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten. 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 risks	• HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) (FTC/TDF) • Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication) (FTC/TDF)

	• Renal toxicity [tenofovir disoproxil fumarate (TDF)] • Bone events due to proximal renal tubulopathy/loss of bone mineral density (TDF)
Important potential risks	• None
Missing information	• Safety in pregnancy and lactation (TDF)

II.B Summary of important risks

Important identified risks

HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) (FTC/TDF)	
Risk minimisation measures	**Routine risk minimisation measures:** • SmPC sections 4.4, 5.1 • PL sections 2, 3 • Information on regular counselling for adherence provided in section 4.4 • Pack size: – Blister packs of 30 x 1 and 90 x 1 tablets. – HDPE bottles containing desiccant, with polypropylene child resistant closure containing 30 tablets • Medicinal product subject to restricted medical prescription **Additional risk minimisation measures:** • Educational material for physicians and patients in the form of: • PrEP indication education program for prescribers
Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication) (FTC/TDF)	
Risk minimisation measures	**Routine risk minimisation measures:** • SmPC sections 4.3, 4.4, 5.1 • PL sections 2, 3 • Information on regular reconfirmation of patients to be HIV-negative at frequent intervals provided in section 4.4 • Pack size: – Blister packs of 30 x 1 and 90 x 1 tablets. – HDPE bottles containing desiccant, with polypropylene child resistant closure containing 30 tablets • Medicinal product subject to restricted medical prescription

	Additional risk minimisation measures: • Educational material for physicians and patients in the form of: • PrEP indication education program for prescribers
Renal toxicity (TDF)	

Risk minimisation measures	**Routine risk minimisation measures:**
	• SmPC sections 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3
	• PL sections 2, 4
	• Recommendations in SmPC section 4.2, 4.4, 4.5, 4.8
	• Pack size:
	  – Blister packs of 30 x 1 and 90 x 1 tablets.
	  – HDPE bottles containing desiccant, with polypropylene child resistant closure containing 30 tablets
	• Medicinal product subject to restricted medical prescription
	Additional risk minimisation measures:
	• Educational material for physician in the form of:
	  – PrEP indication education guide for prescribers, which includes
	  – HIV paediatric renal educational brochure

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 Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten.

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

There are no studies required for Emtricitabin / Tenofovirdisoproxil Tillomed 200 mg / 245 mg Filmtabletten.