Safety concern	Risk minimisation measures	Pharmacovigilance activities
	Additional risk minimisation measures: None.	

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Safety in lactation	Routine risk minimisation measures: Section 4.6 of Emtricitabine/Tenofovir disoproxil fumarate SmPC and corresponding section of PIL have information on this safety concern. Other routine risk minimisation measures including the prescription only status of the product. Additional risk minimisation measures: None.	No additional Pharmacovigilance activities

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Safety in patients with renal impairment	Routine risk minimisation measures: Section 4.2, 4.4, 4.5 4.8 and 5.2 of Emtricitabine/Tenofovir disoproxil fumarate SmPC and corresponding section of PIL have information on this safety concern. Other routine risk minimisation measures including the prescription only status of the product. Additional risk minimisation measures: None.	No additional Pharmacovigilance activities

Part VI: Summary of the risk management plan

Summary of risk management plan for (Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets)

This is a summary of the risk management plan (RMP) for Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets. 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 fumarate 200 mg/245 mg film-coated tablet's risks and uncertainties (missing information).

Emtricitabine/Tenofovir disoproxil tablet's SmPC and PIL give essential information to healthcare professionals and patients on how Emtricitabine/Tenofovir disoproxil fumarate 200 mg/245 mg film-coated tablets 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 indicated antiretroviral combination therapy for the treatment of HIV-1 infected adults, 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 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 fumarate as the active substance and it is given by orally.

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

Important risks of Emtricitabine/Tenofovir disoproxil fumarate, together with measures to minimise such risks and learning more about Emtricitabine/Tenofovir disoproxil fumarate 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 leaflets and SmPCs 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.

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 fumarate are risks that need special risk management activities to further investigate or minimise 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 Emtricitabine/Tenofovir disoproxil fumarate. 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.

Summary of safety concerns	
Important identified risks	• Post-treatment hepatic flares in HBV infected patients • 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) • Renal toxicity • Bone events due to proximal renal tubulopathy/loss of bone mineral density • Interaction with didanosine • Pancreatitis
Important potential risks	None
Important missing information	• Safety in children (including long-term safety) • Safety in pregnancy • Safety in elderly patients • Safety in lactation • Safety in patients with renal impairment

II.B Summary of important risks

Important Identified Risks: HIV-1 acquisition, including infection resulting from non-adherence	
Risk minimisation measures	Routine risk minimisation measures: Section 4.4 of Emtricitabine/Tenofovir SmPC have information on this safety concern. Other routine risk minimisation measures including the prescription only status of the product. Additional risk minimisation measures: Distribution of risk minimization material directed to the prescriber and the individual at risk, to healthcare providers who are likely to prescribe Emtricitabine/Tenofovir disoproxil for PrEP.

Important Identified Risks: Development of resistance in patients with unrecognized or acute HIV-1 infection

Risk minimisation measures	Routine risk minimisation measures: Section 4.3, 4.4 and 5.1 of Emtricitabine/Tenofovir SmPC have information on this safety concern. Other routine risk minimisation measures including the prescription only status of the product. Additional risk minimisation measures: Distribution of risk minimization material directed to the prescriber and the individual at risk, to healthcare providers who are likely to prescribe Emtricitabine/Tenofovir disoproxil for PrEP

Important Identified Risks: Renal toxicity	
Risk minimisation measures	Routine risk minimisation measures: Section 4.4 and 4.8 of Emtricitabine/Tenofovir disoproxil SmPC have information on this safety concern. Other routine risk minimisation measures including the prescription only status of the product. Additional risk minimisation measures: HIV renal educational brochure for prescribers of

II.C Post-authorisation development plan

No post authorisation study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or which are a specific obligation of Emtricitabine/Tenofovir disoproxil fumarate.

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

There are no studies required for Emtricitabine/Tenofovir disoproxil fumarate.