

Part VI: Summary of the risk management plan

Emtricitabine/Tenofovir disoproxil film-coated tablets 200/245 mg, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten (emtricitabine/tenofovir disoproxil)

This is a summary of the risk management plan (RMP) for Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten. The RMP details important risks of Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten, how these risks can be minimised, and how more information will be obtained about Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablet, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten's risks and uncertainties (missing information).

Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablet, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten should be used.

Important new concerns or changes to the current ones will be included in updates of Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablet, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten's RMP.

I. The medicine and what it is used for

Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten are indicated for below indications:

Treatment of HIV-1 infection:

- 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

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

They contain emtricitabine/tenofovir disoproxil as the active substances and are given by oral route.

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

Important risks of Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten, together with measures to minimise such risks and the proposed studies for learning more about Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten' 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 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 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 Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten are 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 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 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 Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 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)

Important identified risks	<ul style="list-style-type: none"> • HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) (ETZ)
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	<ul style="list-style-type: none"> • Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication) (ETZ)
Important potential risks	<ul style="list-style-type: none"> • None
Missing information	<ul style="list-style-type: none"> • Safety in pregnancy and lactation (TD)

TD = Tenofovir disoproxil

ETZ = Emtricitabine

II.B Summary of important risks

Important Identified Risk: HIV-1 acquisition, including infection resulting from non-adherence	
Risk minimisation measures	<p><u>Routine risk minimisation measures:</u></p> <ul style="list-style-type: none"> • SmPC Section 4.4 • PIL sections 2 <p><u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u></p> <ul style="list-style-type: none"> • HIV-1 uninfected individuals should be counselled at frequent intervals to strictly adhere to the recommended emtricitabine/tenofovir daily dosing schedule is included in SmPC section 4.4 • While taking emtricitabine/tenofovir to reduce the risk of getting HIV, it was recommended to take emtricitabine/tenofovir every day to reduce your risk, not just when you think you have been at risk of HIV infection. Do not miss any doses of emtricitabine/tenofovir, or stop taking it. Missing doses may increase your risk of getting HIV infection is mentioned in PIL section 2. <p><u>Other routine risk minimisation measures beyond the product information:</u></p> <p>The prescription only status of the product.</p> <p><u>Additional risk minimisation measures:</u></p> <p>Physician educational pack containing:</p> <ul style="list-style-type: none"> – PrEP educational brochure for prescribers entitled ‘Important Safety Information for Prescribers about

	<p>Emtricitabine/Tenofovir disoproxil for a Pre-exposure Prophylaxis (PrEP) Indication’</p> <ul style="list-style-type: none"> – PrEP Checklist for prescribers – PrEP educational brochure for the individual at risk entitled ‘Important Information About Emtricitabine/Tenofovir disoproxil to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection’ – PrEP reminder card
<p>Important Identified Risk: Development of resistance in patients with unrecognised or acute HIV-1 infection</p>	
<p>Risk minimisation measures</p>	<p><u>Routine risk minimisation measures:</u></p> <ul style="list-style-type: none"> • SmPC Sections 4.3 and 4.4 • PIL section 2 <p><u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u></p> <ul style="list-style-type: none"> • Individuals should be re-confirmed to be HIV-negative at frequent intervals (e.g. at least every 3 months) using a combined antigen/antibody test while taking emtricitabine/tenofovir for pre-exposure prophylaxis is included in SmPC section 4.4. • If clinical symptoms consistent with acute viral infection are present and recent (< 1 month) exposures to HIV-1 are suspected, use of emtricitabine/tenofovir should be delayed for at least one month and HIV-1 status reconfirmed before starting treatment for pre-exposure prophylaxis which is mentioned in SmPC section 4.4. • While taking emtricitabine/tenofovir to reduce the risk of getting HIV, it was recommended to get tested for HIV regularly is mentioned in PIL section 2. <p><u>Other routine risk minimisation measures beyond the product information:</u></p> <p>The prescription only status of the product.</p> <p><u>Additional risk minimisation measures:</u></p> <p>Physician educational pack containing:</p> <ul style="list-style-type: none"> – PrEP educational brochure for prescribers entitled ‘Important Safety Information for Prescribers about Emtricitabine/Tenofovir disoproxil for a Pre-exposure Prophylaxis (PrEP) Indication’ – PrEP Checklist for prescribers

	<ul style="list-style-type: none"> – PrEP educational brochure for the individual at risk entitled ‘Important Information About Emtricitabine/Tenofovir disoproxil to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection’ – PrEP reminder card
Missing information: Safety in pregnancy and lactation	
Risk minimisation measures	<p><u>Routine risk minimisation measures:</u></p> <ul style="list-style-type: none"> – SmPC Section 4.6 – PIL section 2 <p><u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u></p> <p>None</p> <p><u>Other routine risk minimisation measures:</u></p> <p>The labelling and the prescription only status of the product.</p> <p><u>Additional risk minimisation measures:</u></p> <ul style="list-style-type: none"> – None

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 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten.

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

There are no studies required for Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets, Emtricitabine/Tenofovir disoproxil Accord pharma 200 mg/245 mg film-coated tablets & Emtricitabin/Tenofovir disoproxil fumarate Accord 200/245 mg Filmtabletten.