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## Part VI: Summary of the risk management plan

### Summary of risk management plan for Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg (Emtricitabine and Tenofovir Alafenamide Succinate)

This is a summary of the Risk Management Plan (RMP) for Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg. The RMP details important risks of Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg, how these risks can be minimised, and how more information will be obtained about Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg's risks and uncertainties (missing information).

Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200mg/10mg and 200 mg/25 mg should be used.

#### I. The medicine and what it is used for

- In EU: Emtricitabine/ Tenofovir Alafenamide Succinate (200 mg/10 mg and 200 mg/25 mg) film coated tablets are indicated in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with HIV-1.
- In UK:
  - Emtricitabine/ Tenofovir Alafenamide Succinate (200 mg/10 mg and 200 mg/25 mg) film coated tablets are indicated in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with HIV-1.
  - Emtricitabine/ Tenofovir Alafenamide Succinate (200 mg/25 mg) film coated tablets are also indicated for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in at-risk men who have sex with men, including adolescents (with body weight at least 35 kg).

It contains Emtricitabine and Tenofovir Alafenamide Succinate Fumarate as the active substances and it is given by oral route.

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

Important risks of Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10mg and 200 mg/25 mg, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg are:

- 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; and how to use Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg.
- 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 - Prescription only medicine.

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 Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg 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 Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg 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 Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg. 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	<ul style="list-style-type: none"><li>• None</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• None</li></ul>
Missing information	<ul style="list-style-type: none"><li>• Safety in pregnancy and lactation</li></ul>

## II.B Summary of important risks

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

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## **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 Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg.

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

There are no studies required of Emtricitabine/ Tenofovir Alafenamide Succinate film-coated tablets 200 mg/10 mg and 200 mg/25 mg.