Summary of the Risk Management Plan

Risk management plan for Tenofovir disoproxil Zentiva

This is a summary of the risk management plan (RMP) for Tenofovir disoproxil Zentiva 245 mg film-coated tablets. The RMP details important risks of Tenofovir disoproxil Zentiva 245 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Tenofovir disoproxil Zentiva 245 mg film-coated tablets risks and uncertainties (missing information).
Tenofovir disoproxil Zentiva 245 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tenofovir disoproxil Zentiva 245 mg film-coated tablets should be used.

This summary of the RMP for Tenofovir disoproxil Zentiva 245 mg film-coated tablets 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 Tenofovir disoproxil Zentiva 245 mg film-coated tablets RMP.

I. The medicine and what it is used for

Tenofovir disoproxil Zentiva 245 mg film-coated tablets is authorised for HIV 1 infection and hepatitis B infection in adults and adolescents aged 12 to < 18 years (see SmPC for the full indication). It contains tenofovir disoproxil as the active substance and it is given orally.

Further information about the evaluation of Tenofovir disoproxil Zentiva 245 mg film-coated tablets benefits can be found in Tenofovir disoproxil Zentiva 245 mg film-coated tablets 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/tenofovir-disoproxil-zentiva.

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

Important risks of Tenofovir disoproxil Zentiva 245 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Tenofovir disoproxil Zentiva 245 mg film-coated tablets 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 Tenofovir disoproxil Zentiva 245 mg film-coated tablets, 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, including PSUR assessment, 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 Tenofovir disoproxil Zentiva 245 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tenofovir disoproxil Zentiva 245 mg film-coated tablets 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 Tenofovir disoproxil Zentiva 245 mg film-coated tablets. 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	• Renal Toxicity • Bone events due to proximal renal tubulopathy / loss of bone mineral density
Important potential risks	None
Missing information	• Safety in pregnancy and lactation • Safety in patients with renal impairment

II.B Summary of important risks

Renal Toxicity	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC section 4.4, 4.8, 5.1 and 5.3 PL section 2 and 4 Recommendation for renal function monitoring is included in section 4.4 and 4.8 of SmPC and PL section 2 Prescription only medicine. Therapy should be initiated by a physician experienced in the management of HIV infection and/or treatment of chronic hepatitis B. <u>Additional risk minimisation measures</u> Educational program for physicians

Bone events due to proximal renal tubulopathy / loss of bone mineral density	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.4, 4.8, 5.1 and 5.3 PL section 2 and 4 Recommendation for consultation with specialist (endocrinologist and or/nephrologist) in case that bone abnormalities are detected

Bone events due to proximal renal tubulopathy / loss of bone mineral density	
	or suspected in paediatric patients is included in section 4. 4 of SmPC and PL section 2 Prescription only medicine. Therapy should be initiated by a physician experienced in the management of HIV infection and/or treatment of chronic hepatitis B. <u>Additional risk minimisation measures:</u> Educational program for physicians

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 Tenofovir disoproxil Zentiva 245 mg film-coated tablets.

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

There are no studies in post-authorisation development plan for Tenofovir disoproxil Zentiva 245 mg film-coated tablets.