

Part VI: Summary of the risk management plan

Summary of risk management plan for Tenbera 25 mg & 50 mg filmdragerade tabletter and Dolutegravir ELPEN 25 mg & 50 mg filmdragerade tabletter (dolutegravir)

This is a summary of the risk management plan (RMP) for Tenbera 25 mg & 50 mg filmdragerade tabletter and Dolutegravir ELPEN 25 mg & 50 mg filmdragerade tabletter [Tenbera, Dolutegravir ELPEN]. The RMP details important risks of Tenbera, Dolutegravir ELPEN, how these risks can be minimised, and how more information will be obtained about Tenbera, Dolutegravir ELPEN's risks and uncertainties (missing information).

Tenbera, Dolutegravir ELPEN's summary of product characteristics (SmPC) and their package leaflet give essential information to healthcare professionals and patients on how Tenbera, Dolutegravir ELPEN should be used.

Important new concerns or changes to the current ones will be included in updates of Tenbera, Dolutegravir ELPEN's RMP.

I. The medicine and what it is used for

Tenbera, Dolutegravir ELPEN are authorised in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, adolescents and children of at least 6 years of age or older and weighing at least 14 kg.

They contain dolutegravir as the active substance and they are given orally.

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

Important risks of Tenbera, Dolutegravir ELPEN, together with measures to minimise such risks and the proposed studies for learning more about Tenbera, Dolutegravir ELPEN'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 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 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 Tenbera, Dolutegravir ELPEN is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tenbera, Dolutegravir ELPEN 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 Tenbera, Dolutegravir ELPEN. 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	None
Important potential risks	• Neural tube defects
Missing information	• Use in pregnancy/breastfeeding

II.B Summary of important risks

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

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 Tenbera, Dolutegravir ELPEN.

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

There are no studies required for Tenbera, Dolutegravir ELPEN.