Part VI: Summary of the risk management plan

Summary of risk management plan for Raltegravir Zentiva 600 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Raltegravir Zentiva. The RMP details important risks of Raltegravir Zentiva and how more information will be obtained about Raltegravir Zentiva risks and uncertainties (missing information).

Raltegravir Zentiva´s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Raltegravir Zentiva should be used.

Important new concerns or changes to the current ones will be included in updates of Raltegravir Zentiva´s RMP.

I. The medicine and what it is used for

Raltegravir Zentiva is authorised in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, and paediatric patients weighing at least 40 kg

It contains raltegravir as the active substance and is given orally.

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

Important risks of Raltegravir Zentiva, together with measures to minimise such risks and the proposed studies for learning more about Raltegravir Zentiva´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 Raltegravir Zentiva is not yet available, it is listed under ‘missing information’ below

II.A List of important risks and missing information

Important risks of Raltegravir Zentiva 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 Raltegravir Zentiva. 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	None
Missing information	Safety of 1200 mg once daily (QD) (2x 600mg tablets) dosing in pregnant women

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 Raltegravir Zentiva.

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

There are no studies required for Raltegravir Zentiva.