Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Dolutegravir sodium Teva (dolutegravir sodium)

This is a summary of the risk management plan (RMP) for Dolutegravir sodium Teva (hereinafter referred to as Dolutegravir sodium). The RMP details important risks of Dolutegravir sodium, how these risks can be minimised, and how more information will be obtained about Dolutegravir sodium's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Dolutegravir sodium is 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 (see SmPC for the full indication). It contains Dolutegravir sodium as the active substance and it is given orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

II.A List of Important Risks and Missing Information

Important risks of Dolutegravir sodium 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 Dolutegravir sodium. 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).

Table 6: Summary of Safety Concerns

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• Neural tube defects
Missing information	• Use in pregnancy/breastfeeding

II.B Summary of Important Risks

Table 7: Summary of Pharmacovigilance Activities and/or Additional Risk Minimisation Activities by Safety Concern

Important potential risk: Neural tube disorders	
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Antiretroviral pregnancy registry See section II.C of this summary for an overview of the post-authorisation development plan.
Missing information: Use in pregnancy/breastfeeding	
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Antiretroviral pregnancy registry See section II.C of this summary for an overview of the post-authorisation development plan.

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 Dolutegravir sodium.

II.C.2 Other Studies in Post-Authorisation Development Plan

The following study is a required additional pharmacovigilance activity:

Antiretroviral Pregnancy Registry (APR)

Purpose of the study:

The APR is an international registry that monitors prenatal exposures to ARV drugs to detect a potential increase in the risk of birth defects through a prospective exposure registration cohort. The APR is a collaborative effort of multiple companies [Antiretroviral Pregnancy Registry 2023]. Data from the APR is used to monitor use of the Dolutegravir in pregnancy.