PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for PREZISTA (Darunavir [TMC114])

This is a summary of the risk management plan (RMP) for PREZISTA. The RMP details important risks of PREZISTA, how these risks can be minimized, and how more information will be obtained about PREZISTA's risks and uncertainties (missing information).

PREZISTA's Summary of Product Characteristics (SmPC) and its package leaflet provide essential information to healthcare professionals and patients on how PREZISTA should be used.

This summary of the RMP for PREZISTA 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.

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

I. The Medicine and What it is Used For

PREZISTA coadministered with low-dose ritonavir (darunavir [DRV]/rtv) or PREZISTA coadministered with cobicistat (DRV/COBI) is authorized in combination with other antiretroviral medicines for the treatment of patients with human immunodeficiency virus type 1 (HIV-1) infection (see SmPC for the full indication). PREZISTA contains DRV (or TMC114) as the active substance and is given as an oral tablet (DRV 75 mg, 150 mg, 400 mg, 600 mg, 800 mg) or oral suspension (DRV 100 mg/mL).

Further information about the evaluation of PREZISTA’s benefits can be found in PREZISTA’s European Public Assessment Report, including in its plain-language summary, available on the European Medicines Agency website, under the medicine’s webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/prezista.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of PREZISTA, together with measures to minimize such risks and the proposed studies for learning more about PREZISTA's risks, are outlined below.

Measures to minimize 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 authorized 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed including Periodic Benefit-Risk Evaluation Report/Periodic Safety Update Report 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 PREZISTA is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of PREZISTA are risks that need special risk management activities to further investigate or minimize 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 PREZISTA. 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 (eg, 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	Long-term safety data in children from 3 to <6 years of age (DRV/rtv)

II.B. Summary of Important Risks

Missing information: Long-term safety data in children from 3 to <6 years of age (DRV/rtv)	
Risk minimization measures	Routine risk minimization measures: • SmPC Section 4.8 • SmPC Section 5.1 • Legal status: restricted medical prescription Additional risk minimization measures: • None

II.C. Postauthorization Development Plan

II.C.1. Studies Which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of PREZISTA.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for PREZISTA.