## Summary of Risk Management Plan for REZOLSTA

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

REZOLSTA's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how REZOLSTA should be used.

This summary of the RMP for REZOLSTA 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 REZOLSTA's RMP.

## I. The Medicine and What it is Used For

REZOLSTA is authorized in combination with other antiretroviral (ARV) medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older, weighing at least 40 kg) (see SmPC for the full indication). REZOLSTA contains darunavir/cobicistat (DRV/COBI) as the active substance and is given as an oral tablet (DRV 800 mg, COBI 150 mg).

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

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

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

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

## II.A. List of Important Risks and Missing Information

Important risks of REZOLSTA 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 REZOLSTA. 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 | Safety in patients with cardiac conduction disorders |

## II.B. Summary of Important Risks

| **Missing Information: Safety in patients with cardiac conduction disorders** | |
|---|---|
| Risk minimization measures | Routine risk minimization measures:<br>• Legal status: restricted medical prescription<br>Additional risk minimization measures:<br>• None |

## II.C. Post-authorization 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 REZOLSTA.

### II.C.2. Other Studies in Post-authorization Development Plan

There are no other studies in the post-authorization development plan of REZOLSTA.