Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Darunavir Glenmark (Darunavir)

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

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

This summary of the RMP for Darunavir Glenmark 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 (EPAR).

Important new concerns or changes to the current ones will be included in updates of Darunavir Glenmark RMP.

I. The medicine and what it is used for

Darunavir Glenmark is authorised for treatment of human immunodeficiency virus (HIV-1) infection.

It contains Darunavir as the active substance and it is given by mouth (orally).

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

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

II.A. List of important risks and missing information

Important risks of Darunavir Glenmark 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 Darunavir Glenmark. 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 risk(s)	1. Severe skin reactions 2. Hepatotoxicity 3. Hyperglycaemia 4. Lipid abnormalities 5. Immune reconstitution inflammatory syndrome 6. Development of drug resistance 7. Overdose due to medication error 8. Drug-drug interactions
Important potential risk(s)	1. Coronary artery events 2. Off-Label use of DRV/COBI in paediatric population and in ARV Treatment-experienced Patients with HIV-1 RNA >100,000 copies/mL
Missing information	1. Elderly (65 years and above) 2. Subjects with renal impairment 3. Subjects with severe hepatic impairment (Child-Pugh C) **Darunavir/Rotonavir** 4. Long term safety data in children from 3 to < 6 years of age **Darunavir/Cobicistat**

	5. Children <18 years of age 6. Use in virologically suppressed pregnant women 7. Long-term safety of DRV/COBI in adults 8. Subjects co-infected with HIV and HBV and/or HCV

II.B. Summary of important risk

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 Darunavir Glenmark.

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

There are no studies required for Darunavir Glenmark.