Part VI: Summary of the risk management plan

Summary of risk management plan for Darunavir Dr. Reddy's (darunavir)

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

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

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

I. The medicine and what it is used for

Darunavir Dr. Reddy's is indicated for use together with low-dose ritonavir and other HIV medicines to treat adults and children aged three years or over who are infected with human immunodeficiency virus (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). In adults, Darunavir Dr. Reddy's 400 mg and 800 mg is also used with another medicine, cobicistat, in combination with other HIV medicines to treat HIV-1 infection (see the SmPCs for the full indications).

It contains darunavir as the active substance and it is taken by mouth.

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

Important risks of Darunavir Dr. Reddy's, together with measures to minimise such risks and the proposed studies for learning more about Darunavir Dr. Reddy'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 leaflets and SmPCs 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 Darunavir Dr. Reddy's is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Darunavir Dr. Reddy's 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 Dr. Reddy's. 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).

Summary of safety concerns	
Important identified risks	• Severe skin reactions • Hepatotoxicity • Hyperglycaemia • Lipid abnormalities • • Immune reconstitution inflammatory syndrome • Development of drug resistance • Overdose due to medication error • Drug-drug interactions
Important potential risks	• Growth abnormalities in the paediatric population • Off-label use of DRV/COBI in the paediatric population and in ARV treatment-experienced patients with HIV-1 RNA > 100,000 copies/mL
Missing information	• Older people (65 years and above) • Pregnant and breast-feeding women • Subjects with severe hepatic impairment (Child-Pugh C) • Subjects with renal impairment DRV when used with RTV • Long term safety data in children from 3 to < 6 years of age • Impact of palatability of the oral suspension on adherence and efficacy in treatment-experienced children >15 kg DRV when used with COBI • Children <18 years of age • Long term safety of DRV/COBI in adults • Subjects co-infected with HIV and HBV and/or HCV

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 Darunavir Dr. Reddy's.

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

There are no studies required for Darunavir Dr. Reddy's.