## Summary of the risk management plan

**Summary of risk management plan for Darunavir Mylan (darunavir)**

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

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

This summary of the RMP for Darunavir Mylan should be read in the context of all the 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 Mylan's RMP.

**I. The medicine and what it is used for**

Darunavir Mylan is authorised for:

Darunavir Mylan 75 mg, 150 mg, 300 mg and 600 mg film-coated tablets:

Darunavir, co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of patients with HIV-1 infection.

Darunavir Mylan 75 mg, 150mg, 300mg, 600mg tablets may be used to provide suitable dose regimens:

- For the treatment of HIV-1 infection in antiretroviral treatment (ART)-experienced adult patients, including those that have been highly pre-treated.
- For the treatment of HIV-1 infection in paediatric patients from the age of 3 years and at least 15 kg body weight.

In deciding to initiate treatment with darunavir co-administered with low dose ritonavir, careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of darunavir.

Darunavir Mylan 400 mg and 800 mg film-coated tablets

Darunavir, co-administered with cobicistat is indicated in combination with other antiretroviral medicinal products for the treatment of patients with human immunodeficiency virus (HIV-1) infection.

Darunavir co-administered with cobicistat is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults and adolescents (aged 12 years and older, weighing at least 40 kg).

Darunavir Mylan 400mg and 800 mg tablets may be used to provide suitable dose regimens for the treatment of HIV-1 infection in adult and paediatric patients from the age of 3 years and at least 40 kg body weight who are:

- Antiretroviral therapy (ART)-naïve.
- ART-experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+ cell count ≥ 100 cells x 106/l. In deciding to initiate treatment with darunavir in such ART-experienced patients, genotypic testing should guide the use of darunavir.

It contains darunavir as the active substance and it is given orally.

Further information about the evaluation of Darunavir Mylan's benefits can be found in Darunavir Mylan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage (https://www.ema.europa.eu/en/documents/overview/darunavir-mylan-epar-summary-public_en.pdf).

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

Important risks of Darunavir Mylan, together with measures to minimise such 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 public (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 events 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 Mylan is not yet available, it is listed under 'missing information' below.

**II.A List of important risks and missing information**

Important risks of Darunavir Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Mylan. 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/use in special patient populations etc.);

Summary of safety concerns

| **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 (Darunavir/Ritonavir) |

**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 Mylan.

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

There are no studies required for Darunavir Mylan.