10 November 2016
EMA/CHMP/573531/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Darunavir Mylan

darunavir

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Darunavir Mylan, intended for the treatment of human immunodeficiency virus (HIV-1) infection. The applicant for this medicinal product is Mylan S.A.S.

Darunavir Mylan will be available as film-coated tablets (75 mg, 150 mg, 300 mg, 400 mg, 600 mg and 800 mg). The active substance of Darunavir Mylan is darunavir, a protease inhibitor (ATC code: J05AE10). It acts by inhibiting the HIV enzyme protease, thus preventing formation of mature virus. Darunavir must be given with a small dose of ritonavir or cobicistat (as a booster), which decreases the breakdown of darunavir in the liver, resulting in higher levels of darunavir in the blood.

Darunavir Mylan is a generic of Prezista, which has been authorised in the EU since 12 February 2007. Studies have demonstrated the satisfactory quality of Darunavir Mylan and its bioequivalence to the reference product Prezista. A question and answer document on generic medicines can be found here.

The full indication is:

75 mg, 150 mg, 300 mg, 600 mg tablets

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

Darunavir Mylan tablets may be used to provide suitable dose regimens (see section 4.2):

- 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

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of daranuvir."

400 mg and 800 mg tablets

"Darunavir co-administered with low dose ritonavir 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 adult patients (see section 4.2).

Darunavir Mylan 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 (see section 4.2).
- 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 (see sections 4.2, 4.3, 4.4 and 5.1)."

It is proposed that Darunavir Mylan be initiated by a health care provider experienced in the management of HIV infection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.