EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2017
EMA/CHMP/729969/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Darunavir Krka d.d.

darunavir

On 9 November 2017, 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 Krka d.d., intended for the treatment of human immunodeficiency virus (HIV-1) infection. The applicant for this medicinal product is Krka, d.d., Novo mesto.

Darunavir Krka d.d. will be available as film-coated tablets (400 mg, 600 mg and 800 mg). The active substance of Darunavir Krka d.d. is darunavir, a protease inhibitor (ATC code: J05AE10). It acts by inhibiting the HIV enzyme protease, thus preventing formation of mature virus.

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

The full indication for the 400 mg and 800 mg tablets is:

> "Darunavir Krka d.d., 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.
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> Darunavir Krka d.d., 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 in adult patients (see section 4.2).

[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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Darunavir Krka d.d. 400 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 (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 10^6/l. In deciding to initiate treatment with Darunavir Krka d.d. in such ART-experienced patients, genotypic testing should guide the use of Darunavir Krka d.d. (see sections 4.2, 4.3, 4.4 and 5.1)."

The full indication for the 600 mg tablets is:

"Darunavir Krka d.d., 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 Krka d.d. 600 mg 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 mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of darunavir."

It is proposed that Darunavir Krka d.d. be initiated by physicians 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.