EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2011
EMA/CHMP/51975/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Prezista

darunavir

On 20 January 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Prezista. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:

"Prezista 400 mg tablets may be used to provide suitable dose regimens:

For the treatment of HIV-1 infection in ART-experienced adults 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 Prezista in such ART-experienced adults genotypic testing should guide the use of Prezista."

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

For information, the full indications for Prezista 400mg tablets will be as follows[2]:

"Prezista, 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.

Prezista 400 mg tablets may be used to provide suitable dose regimens (see section 4.2):

- For the treatment of HIV-1 infection in antiretroviral therapy (ART) naïve adults.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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- **For the treatment of HIV-1 infection in ART-experienced adults 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 PREZISTA in such ART-experienced adults genotypic testing should guide the use of PREZISTA (see sections 4.2, 4.3, 4.4 and 5.1).”**