EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 September 2014
EMA/CHMP/580222/2014 Rev. 1 - EMEA/H/C/000707/II/0063
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Prezista

Darunavir

On 25 September 2014, 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 100mg /ml oral suspension; 400 mg and 800 mg film-coated tablets. 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 75/150/300/600 mg tablets may be used to provide suitable dose regimens for the treatment of HIV-1 infection in paediatric patients from the age of 3 years and at least 15 kg body weight.”

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 indication(s) for PREZISTA will be as follows[2]:

75/150/300/600 mg tablets

“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 75/150/300/600 mg 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 pretreated;

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- for the treatment of HIV-1 infection in paediatric patients from the age of three years and at least 15 kg body weight.

400/800 mg tablets

"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, 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).

Prezista 400/800 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 12 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 10^6/l. In deciding to initiate treatment with PREZISTA in such ART-experienced patients, genotypic testing should guide the use of PREZISTA.

100 mg/ml oral suspension

Prezista, co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult and paediatric patients from the age of 3 years and at least 15 kg body weight (see section 4.2).

PREZISTA, 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).

In deciding to initiate treatment with PREZISTA co-administered with **cobicistat or** 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 PREZISTA."