19 July 2012
EMA/CHMP/487381/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Prezista

darunavir

On 19 July 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending an extension and 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 extension adopted by the CHMP is to add a new pharmaceutical form (100 mg/ml oral suspension) to the existing product range.

The CHMP also adopted a change to an indication, as follows[2]:

"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 patients as well as antiretroviral therapy (ART)-experienced **paediatric patients** from the age of **3** years and at least **15** kg body weight.

In deciding to initiate treatment with PREZISTA 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 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.

[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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