



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 July 2020  
EMA/CHMP/382827/2020  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Prezista darunavir

On 23 July 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Prezista. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted an extension to the existing indication as follows:<sup>2</sup>

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 **adults and adolescents (aged 12 years and older, weighing at least 40 kg)** ~~patients~~ (see section 4.2).

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> **New text in bold, removed text as strikethrough**

