22 May 2025
EMA/CHMP/162393/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rezolsta

darunavir / cobicistat

On 22 May 2025, 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 Rezolsta. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted an extension to the existing indication, as follows:[2]

> REZOLSTA is indicated, in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and ~~adolescents~~ **paediatric patients** (aged ~~12~~ **6** years and older, weighing at least ~~40~~ **25** kg).
>
> Genotypic testing should guide the use of REZOLSTA (see sections 4.2, 4.4 and 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change 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 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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