25 June 2026
EMADOC-1700519818-3224353
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rezolsta

darunavir / cobicistat

On 25 June 2026, 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 N.V.

The CHMP adopted a new pharmaceutical form, dispersible tablets, associated with a new strength (600 mg / 90 mg) and a new indication to include children from 3 years of age weighing at least 15 kg, as follows:

> REZOLSTA is indicated, in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and paediatric patients aged 3 years and older, weighing at least 15 kg.
>
> Genotypic testing should guide the use of REZOLSTA (see sections 4.2, 4.4 and 5.1).

For information, the indication for Rezolsta film-coated tablets remains unchanged, as follows:

> REZOLSTA is indicated, in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and paediatric patients aged 6 years and older, weighing at least 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] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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