25 June 2026
EMADOC-1700519818-3225919
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Symtuza

darunavir / cobicistat / emtricitabine / tenofovir alafenamide

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 Symtuza. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.

The CHMP adopted an extension to the existing indication, associated with a new strength (675 mg / 150 mg / 200 mg / 10 mg film-coated tablets), as follows:[2]

> Symtuza is indicated for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in adults and **paediatric patients**~~adolescents~~ aged **6**~~12~~years and older with body weight at least **25**~~40~~ kg.
>
> Genotypic testing should guide the use of Symtuza (see sections 4.2, 4.4, and 5.1).

For information, the indication for Symtuza will now be:

> Symtuza is indicated for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in adults and paediatric patients aged 6 years and older with body weight at least 25 kg.
>
> Genotypic testing should guide the use of Symtuza (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.

[2] New text in bold, removed text as strikethrough.

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