25 July 2024
EMA/CHMP/326801/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Edurant

Rilpivirine

On 25 July 2024, 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 Edurant. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a new pharmaceutical form, 2.5 mg dispersible tablets, associated with a new indication for the treatment of children from 2 years of age, as follows:

> EDURANT, in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in paediatric patients 2 to less than 18 years of age and weighing at least 14 kg to less than 25 kg without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, and with a viral load ≤ 100,000 HIV-1 RNA copies/ml (see sections 4.4 and 5.1).
>
> Genotypic resistance testing should guide the use of EDURANT (see sections 4.4 and 5.1).

The CHMP also adopted an extension to an existing indication for the already authorised 25 mg film-coated tablets, as follows:[2]

> EDURANT, in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in ~~antiretroviral treatment-naïve~~ **adults and paediatric** patients ~~12 years of age and older~~ **weighing at least 25 kg without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class**, **and** with a viral load ≤ 100,000 HIV-1 RNA copies/ml (see sections 4.4 and 5.1).
>
> Genotypic resistance testing should guide the use of EDURANT (see sections 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 in the revised European public assessment report

[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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(EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.