14 September 2017
EMA/CHMP/603432/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Stribild

elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil

On 14 September 2017, 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 Stribild. The marketing authorisation holder for this medicinal product is Gilead Sciences International Limited.

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

> "Stribild is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild (see sections 4.2, 4.4 and 5.1).
>
> **Stribild is also indicated for the treatment of HIV-1 infection in adolescents aged 12 to < 18 years weighing ≥ 35 kg who are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil fumarate (TDF) (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 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.

[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

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