15 September 2022
EMA/CHMP/765087/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Biktarvy

bictegravir / emtricitabine / tenofovir alafenamide

On 15 September 2022, 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 Biktarvy. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

The CHMP adopted the addition of a new strength (30 mg/120 mg/15 mg, film-coated tablet) and an extension to the existing indication for Biktarvy to include the treatment of paediatric patients from 2 years of age.

For information, the full indication will be as follows:[2]

> Biktarvy is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults **and paediatric patients at least 2 years of age and weighing at least 14 kg** without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir (see section 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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