26 April 2018
EMA/CHMP/228562/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Biktarvy

bictegravir / emtricitabine / tenofovir alafenamide

On 26 April 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Biktarvy, intended for the treatment of HIV-1 infection. The applicant for this medicinal product is Gilead Sciences International Limited.

Biktarvy will be available as a fixed dose combination of three active substances, bictegravir, emtricitabine and tenofovir alafenamide, and will be available as 50 mg, 200 mg, 25 mg film-coated tablets (ATC code: J05AR20). Bictegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration that is essential for the HIV replication cycle. Emtricitabine and tenofovir alafenamide are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination.

The benefits with Biktarvy are its ability to achieve a potent antiretroviral response in a once daily, single pill regimen. The most common side effects are diarrhoea, headache, nausea, fatigue, dizziness and abnormal dreams.

The full indication is: " Biktarvy is indicated for the treatment of adults infected with human immunodeficiency virus 1 (HIV 1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir (see section 5.1)."

It is proposed that Biktarvy be prescribed by physicians experienced in the management of HIV infection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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