22 May 2025
EMA/CHMP/161057/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Emtricitabine/Tenofovir alafenamide Viatris

emtricitabine / tenofovir alafenamide

On 22 May 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Emtricitabine/Tenofovir alafenamide Viatris for the treatment of adults and adolescents infected with human immunodeficiency virus type 1 (HIV-1). The applicant for this medicinal product is Viatris Limited.

Emtricitabine/Tenofovir alafenamide Viatris will be available as 200 mg/25 mg and 200 mg/10 mg film-coated tablets. The active substances of Emtricitabine/Tenofovir alafenamide Viatris are emtricitabine and tenofovir alafenamide, antivirals for treatment of HIV infections (ATC code: J05AR17). They exert their antiviral effects by inhibiting HIV reverse transcriptase through incorporation into the viral DNA resulting in chain termination.

Emtricitabine/Tenofovir alafenamide Viatris is a generic of Descovy, which has been authorised in the EU since 21 April 2016. Studies have demonstrated the satisfactory quality of Emtricitabine/Tenofovir alafenamide Viatris, and its bioequivalence to the reference product Descovy. A question and answer document on generic medicines can be found here.

The full indication is:

> Emtricitabine/Tenofovir alafenamide Viatris is indicated in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1) (see sections 4.2 and 5.1).

Therapy with Emtricitabine/Tenofovir alafenamide Viatris should be initiated by a physician 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 on the EMA website 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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