19 June 2025
EMA/CHMP/200894/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Emtricitabine/rilpivirine/tenofovir alafenamide Viatris

emtricitabine / rilpivirine / tenofovir alafenamide

On 19 June 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/rilpivirine/tenofovir alafenamide Viatris, intended for treatment of adults and adolescents infected with human immunodeficiency virus type 1 (HIV-1). The applicant for this medicinal product is Viatris Limited.

Emtricitabine/rilpivirine/tenofovir alafenamide Viatris will be available as 200 mg / 25 mg / 25 mg film-coated tablets. The active substances of Emtricitabine/rilpivirine/tenofovir alafenamide Viatris are emtricitabine, rilpivirine and tenofovir alafenamide, a combination of antivirals for the treatment of HIV infections (ATC code: J05AR19). 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. Rilpivirine activity is mediated by non-competitive inhibition of HIV reverse transcriptase.

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

The full indication is:

> Emtricitabine/Rilpivirine/Tenofovir Alafenamide Viatris is indicated for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus-1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine and with a viral load ≤ 100 000 HIV-1 RNA copies/mL (see sections 4.2, 4.4 and 5.1).

Treatment with Emtricitabine/rilpivirine/tenofovir alafenamide Viatris should be initiated by a physician experienced in the management of HIV infection.

[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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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.