



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2016
EMA/CHMP/659472/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Emtricitabine/Tenofovir disoproxil Mylan

emtricitabine / tenofovir disoproxil

On 13 October 2016, 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 disoproxil Mylan, intended for the treatment of HIV infection in adults. The applicant for this medicinal product is MYLAN S.A.S.

Emtricitabine/tenofovir disoproxil Mylan contains as active substances the antiretrovirals emtricitabine and tenofovir disoproxil (ATC code: J05AR03). The medicine will be available as film-coated tablets (200 mg/245 mg). Emtricitabine and tenofovir are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination.

Emtricitabine/Tenofovir disoproxil Mylan is a generic of Truvada, which has been authorised in the EU since 21 February 2005. Studies have demonstrated the satisfactory quality of Emtricitabine/Tenofovir disoproxil Mylan, and its bioequivalence to the reference product Truvada. A question and answer document on generic medicines can be found [here](#).

The full indication is:

"Treatment of HIV-1 infection: Truvada is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults".

It is proposed that Emtricitabine/Tenofovir disoproxil Mylan 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

