13 October 2016
EMA/CHMP/659525/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tenofovir disoproxil Mylan

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

Tenofovir disoproxil Mylan contains as active substance the antiretroviral tenofovir disoproxil (ATC code: J05AR03). The medicine will be available as film-coated tablets (245 mg). Tenofovir is a substrate and competitive inhibitor of HIV reverse transcriptase. After phosphorylation, it is incorporated into the viral DNA chain, resulting in chain termination.

Tenofovir disoproxil Mylan is a generic of Viread which has been authorised in the EU since 5 February 2002. Studies have demonstrated the satisfactory quality of tenofovir disoproxil Mylan, and its bioequivalence to the reference product Viread. A question and answer document on generic medicines can be found here.

The full indication is:

> "*HIV-1 infection*
>
> Tenofovir disoproxil 245 mg film-coated tablets are indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults.
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> In adults, the demonstration of the benefit of tenofovir disoproxil in HIV-1 infection is based on results of one study in treatment-naïve patients, including patients with a high viral load (> 100,000 copies/ml) and studies in which tenofovir disoproxil was added to stable background therapy (mainly tritherapy) in antiretroviral pre-treated patients experiencing early virological failure (< 10,000 copies/ml, with the majority of patients having < 5,000 copies/ml).
>
> Tenofovir disoproxil 245 mg film-coated tablets are also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years.
>
> The choice of tenofovir disoproxil to treat antiretroviral-experienced patients with HIV-1 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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should be based on individual viral resistance testing and/or treatment history of patients.

Hepatitis B infection

Tenofovir disoproxil 245 mg film-coated tablets are indicated for the treatment of chronic hepatitis B in adults with:

- compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis (see section 5.1).
- evidence of lamivudine-resistant hepatitis B virus (see sections 4.8 and 5.1).
- decompensated liver disease (see sections 4.4, 4.8 and 5.1).

Tenofovir disoproxil 245 mg film-coated tablets are indicated for the treatment of chronic hepatitis B in adolescents 12 to < 18 years of age with:

- compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis (see sections 4.4, 4.8 and 5.1)."

It is proposed that 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.