28 February 2019
EMA/CHMP/129761/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Viread

tenofovir disoproxil

On 28 February 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Viread. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

The CHMP adopted an extension to the existing indication for Viread 123 mg, 163 mg and 204 mg film-coated tablets as follows:[2]

"***HIV*-1 infection**

… indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with NRTI resistance or toxicities precluding the use of first line agents, aged 6 to < 12 years who weigh from 28 kg to less than 35 kg.

The choice of Viread to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients.

Hepatitis B infection

… indicated for the treatment of chronic hepatitis B in paediatric patients aged 6 to < 12 years who weigh from 28 kg to less than 35 kg, with:

- **compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in paediatric patients, see sections 4.2, 4.4, 4.8 and 5.1.**"

The CHMP also adopted an extension to the existing indication for Viread 33 mg/g granules as follows:[3]

[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
[2] New text in bold
[3] New text in bold, removed text as strikethrough

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

"*HIV-1 infection*

Viread 33 mg/g granules are indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with NRTI resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate.

Viread 33 mg/g granules are also indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate.

In adults, the demonstration of the benefit of Viread 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 Viread 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).

The choice of Viread to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients.

Hepatitis B infection

Viread 33 mg/g granules are indicated for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate 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).

Viread 33 mg/g granules are also indicated for the treatment of chronic hepatitis B in ~~adolescents~~ **paediatric patients** ~~12~~ **2** to < 18 years of age for whom a solid dosage form is not appropriate with:

- compensated liver disease and evidence of immune active disease, i.e. active viral replication, and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in paediatric patients, see sections 4.2, 4.4, 4.8 and 5.1."

No change is made to the indication for Viread 245 mg film-coated tablets.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.