21 March 2013
EMA/CHMP/161713/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Viread

Tenofovir disoproxil fumerate

On 21 March 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Viread. The marketing authorisation holder for this medicinal product is Gilead Sciences International Ltd. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:

"Hepatitis B infection

indicated for the treatment of chronic hepatitis B in adults with

- evidence of lamivudine-resistant hepatitis B virus (see sections 4.8 and 5.1)."

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication(s) for VIREAD will be as follows[2]:

Viread 245 mg film-coated tablets

HIV-1 infection
Viread 245 mg film-coated tablets are indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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).

Viread 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 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 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).

Viread 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).

Viread 33 mg/g granules

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 12 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, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis (see sections 4.4, 4.8 and 5.1).