23 February 2017
EMA/CHMP/75449/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Emtricitabine/Tenofovir disoproxil Krka d.d.

emtricitabine / tenofovir disoproxil

On 23 February 2017, 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 Krka d.d., intended for the treatment of HIV infection. The applicant for this medicinal product is KRKA, d.d., Novo mesto.

Emtricitabine/Tenofovir disoproxil Krka d.d. contains the active substances emtricitabine and tenofovir disoproxil, antivirals for systemic use (ATC code: J05AR03). It will be available as 200 mg/245 mg film-coated tablets. Emtricitabine is a nucleoside analogue of cytidine while tenofovir is a nucleoside monophosphate (nucleotide) analogue of adenosine monophosphate. Both 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 Krka d.d. 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 Krka d.d., and its bioequivalence to the reference product Truvada. A question and answer document on generic medicines can be found here.

The full indication is: "Emtricitabine/Tenofovir disoproxil Krka d.d. is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults". It is proposed that Emtricitabine/Tenofovir disoproxil Krka d.d. 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

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