14 December 2017
EMA/CHMP/812280/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Efavirenz/Emtricitabine/Tenofovir disoproxil Krka

efavirenz / emtricitabine / tenofovir disoproxil

On 14 December 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 Efavirenz/Emtricitabine/Tenofovir disoproxil Krka, intended for the treatment of HIV infection. The applicant for this medicinal product is KRKA, d.d., Novo mesto.

Efavirenz/Emtricitabine/Tenofovir disoproxil Krka contains as active substances the antiretrovirals efavirenz, emtricitabine and tenofovir disoproxil (ATC code: J05AR06). The medicine will be available as film-coated tablets (600 mg/200 mg/245 mg). Efavirenz activity is mediated by non-competitive inhibition of HIV reverse transcriptase, while emtricitabine and tenofovir disoproxil are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination.

Efavirenz/Emtricitabine/Tenofovir disoproxil Krka is a generic of Atripla, which has been authorised in the EU since 13 December 2007. Studies have demonstrated the satisfactory quality of Efavirenz/Emtricitabine/Tenofovir disoproxil Krka and its bioequivalence to the reference product Atripla. A question and answer document on generic medicines can be found here.

The full indication is:

> "Efavirenz/Emtricitabine/Tenofovir disoproxil Krka is a fixed-dose combination of efavirenz, emtricitabine and tenofovir disoproxil. It is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over with virologic suppression to HIV-1 RNA levels of < 50 copies/ml on their current combination antiretroviral therapy for more than three months. Patients must not have experienced virological failure on any prior antiretroviral therapy and must be known not to have harboured virus strains with mutations conferring significant resistance to any of the three components contained in Efavirenz/Emtricitabine/Tenofovir disoproxil Krka prior to initiation of their first antiretroviral treatment regimen.
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> The demonstration of the benefit of efavirenz/emtricitabine/tenofovir disoproxil is primarily

[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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based on 48-week data from a clinical study in which patients with stable virologic suppression on a combination antiretroviral therapy changed to efavirenz/emtricitabine/tenofovir disoproxil. No data are currently available from clinical studies with efavirenz/emtricitabine/tenofovir disoproxil in treatment-naïve or in heavily pretreated patients.

No data are available to support the combination of efavirenz/emtricitabine/tenofovir disoproxil and other antiretroviral agents."

It is proposed that Efavirenz/Emtricitabine/Tenofovir disoproxil Krka 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.