



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Eviplera

emtricitabine / rilpivirine / tenofovir disoproxil

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eviplera, 200 mg of emtricitabine, 25 mg of rilpivirine (as hydrochloride) and 245 mg of tenofovir disoproxil (as fumarate) film-coated tablet, intended for the treatment of human immunodeficiency virus-1 (HIV-1) infection. The applicant for this medicinal product is Gilead Sciences International Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Eviplera is a fixed dose combination of the active substances emtricitabine, rilpivirine (as hydrochloride) and tenofovir disoproxil (as fumarate), a combination of antivirals for treatment of HIV infections (J05AR08). All three substances act by inhibition of HIV-1 reverse transcriptase, an enzyme needed for replication of the virus; rilpivirine hydrochloride is a non-nucleoside reverse transcriptase inhibitor, emtricitabine a nucleoside reverse transcriptase inhibitor, and tenofovir disoproxil fumarate a nucleotide reverse transcriptase inhibitor. Medicinal products containing either the individual active substances or a dual combination have been approved through the centralised procedure for combination antiretroviral therapy of HIV-1 infection.

The benefits of Eviplera are its ability to reduce and maintain the amount of HIV in plasma (viral load) at a low level in patients with viral load  $\leq 100,000$  HIV 1 RNA copies/ml. The most common side effects are nausea, dizziness, abnormal dreams, headache, insomnia and diarrhea.

A pharmacovigilance plan for Eviplera will be implemented as part of the marketing authorisation.

The approved indication is: " Eviplera is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load  $\leq 100,000$  HIV-1 RNA copies/ml. The demonstration of the benefit of the combination emtricitabine, rilpivirine hydrochloride and tenofovir disoproxil fumarate in antiretroviral therapy is based on week 48 safety and efficacy analyses from two randomised, double-blind, controlled Phase III studies in

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



treatment-naïve patients (see section 5.1). As with other antiretroviral medicinal products, genotypic resistance testing should guide the use of Eviplera (see sections 4.4 and 5.1)."

It is proposed that therapy with Eviplera should be initiated by a physician experienced in the management of human immunodeficiency virus (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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Eviplera and therefore recommends the granting of the marketing authorisation.