24 October 2013
EMA/CHMP/656293/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Eviplera

EMTRICITABINE / RILPIVIRINE / TENOFOVIR DISOPROXIL

On 24 October 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 Eviplera. 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 the indication as follows:
"Eviplera is indicated for the treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) **without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine**, and with a viral load ≤100,000 HIV-1 RNA copies/m**L (see sections 4.2, 4.4 and 5.1)**.

As with other antiretroviral medicinal products, genotypic resistance testing **and/or historical resistance data** should guide the use of Eviplera (see sections 4.4 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.

[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.

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