20 October 2011
EMA/CHMP/613927/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Efavirenz Teva

efavirenz

On 20 October 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 Efavirenz Teva 600 mg film-coated tablets indicated in antiviral combination treatment of human immunodeficiency virus 1 (HIV 1) infected adults, adolescents and children 3 years of age and older. The applicant for this medicinal product is Teva Pharma B.V. 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.

The active substance of Efavirenz Teva is efavirenz, a non-nucleoside reverse transcriptase inhibitor (ATC Code: J05A G03). Efavirenz is a non-competitive inhibitor of HIV-1 reverse transcriptase (RT) and does not significantly inhibit HIV-2 RT or cellular DNA polymerases (α, β, γ or δ).

Efavirenz Teva is a generic of Sustiva, which has been authorised in the EU since 28 May 1999. Studies have demonstrated the satisfactory quality of Efavirenz Teva, and its bioequivalence with the reference product Sustiva. A question and answer document on generic medicines can be found here.

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

The approved is indicated in antiviral combination treatment of human immunodeficiency virus 1 (HIV 1) infected adults, adolescents and children 3 years of age and older.

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