European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 September 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
NEVIRAPINE TEVA

International Nonproprietary Name (INN): ***nevirapine***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Nevirapine Teva, 200mg tablets, indicated in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children of any age.

The applicant for this medicinal product is Teva Pharma B.V.

The active substance of Nevirapine Teva is nevirapine (J05AG01), a non-nucleoside reverse transcriptase inhibitor which acts through non-competitive binding to the HIV RT enzyme blocking the RNA dependent and DNA-dependent DNA polymerase activities by causing a disruption of the enzyme catalytic site.

Nevirapine Teva is a generic of Viramune, which has been authorised in the EU since 5 February 1998. Studies have demonstrated the satisfactory quality of Nevirapine Teva, and its bioequivalence with Viramune. A question-and-answer document on generic medicines can be found here.

A pharmacovigilance plan for Nevirapine Teva, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children of any age.
Most of the experience with nevirapine is in combination with nucleoside reverse transcriptase inhibitors (NRTIs). The choice of a subsequent therapy after nevirapine should be based on clinical experience and resistance testing.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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.

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

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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