18 November 2010
EMA/725978/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Lamivudine / Zidovudine Teva

lamivudine / zidovudine

On 18 November 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lamivudine / Zidovudine Teva 150mg/300mg film-coated tablets intended in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection. The applicant for this medicinal product is Teva Pharma B.V.

The active substances of Lamivudine / Zidovudine Teva are lamivudine and zidovudine, two nucleoside analogues which have activity against HIV (ATC code: J05AR01). Their main modes of action are as chain terminators of viral reverse transcription.

Lamivudine / Zidovudine Teva is a generic of Combivir which has been authorised in the EU since 18 March 1998. Studies have demonstrated the satisfactory quality of Lamivudine / Zidovudine Teva, and its bioequivalence with Combivir. A question-and-answer document on generic medicines can be found here.

The approved indication is: “antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection”. It is proposed that Lamivudine / Zidovudine Teva is 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 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 there to be a favourable benefit to risk balance for Lamivudine / Zidovudine Teva and therefore recommends the granting of the marketing authorisation.

[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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