20 May 2010
EMA/CHMP/329063/2010
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zeffix

lamivudine

On 20 May 2010 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 Zeffix. The marketing authorisation holder for this medicinal product is Glaxo Group 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[2]:

Zeffix is indicated for the treatment of chronic hepatitis B in adults with

- Compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and/or fibrosis**. Initiation of lamivudine treatment should only be considered when the use of an alternative antiviral agent with a higher genetic barrier to resistance is not available or appropriate (see section 5.1).**
- Decompensated liver disease, **in combination with a second antiviral agent without cross-resistance to lamivudine (see section 4.2).**

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.
[2] The text in bold represents the changes in the indication.

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