



16 February 2012
EMA/CHMP/123824/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Sebivo

telbivudine

On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the renewal of the marketing authorisation for the medicinal product Sebivo. The marketing authorisation holder for this medicinal product is Novartis Europharm 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 an indication as follows:

Initiation of Sebivo 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.

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.

For information, the full indications for Sebivo will be as follows²:

Sebivo is indicated for the treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.

Initiation of Sebivo 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 for details of the study and specific patient characteristics on which this indication is based.

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 new or the amended indication.

