



26 June 2014
EMA/CHMP/373218/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Triumeq

abacavir sulfate / dolutegravir sodium / lamivudine

On 26 June 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Triumeq, 50, 600, and 300 mg, film-coated tablet intended for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age weighing at least 40 kg. The applicant for this medicinal product is ViiV Healthcare UK Limited. 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 substances of Triumeq are dolutegravir / abacavir / lamivudine, antivirals for treatment of HIV infections (J05AR13). Dolutegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral Deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle. Abacavir and lamivudine are substrates and competitive inhibitors of HIV reverse transcriptase and their main antiviral activity is through incorporation of the monophosphate form into the viral DNA chain, resulting in chain termination.

The benefits with Triumeq are its ability to achieve potent antiretroviral response, with a high barrier to resistance in a once daily, single pill regimen. The most common side effects are headache, diarrhoea, nausea, insomnia, fatigue and hypersensitivity.

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

The approved indication is: "Triumeq is indicated for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg (see sections 4.4 and 5.1).

Before initiating treatment with abacavir-containing products, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin (see section 4.4). Abacavir should not be used in patients known to carry the HLA-B*5701 allele."

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.



It is proposed that Triumeq be prescribed by physicians experienced in the treatment 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 made 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 Triumeq and therefore recommends the granting of the marketing authorisation.