21 May 2015
EMA/CHMP/277547/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Evotaz

atazanavir / cobicistat

On 21 May 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Evotaz (300 mg/150 mg) film coated tablets, intended for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Evotaz is a fixed dose combination of the antiretroviral medicinal product atazanavir and the pharmacokinetic enhancer cobicistat. The active substance of Evotaz is atazanavir, an HIV-1 protease inhibitor [Antivirals for systemic use, antivirals for treatment of HIV infection, combinations (ATC code: J05AR15)].

The benefits with Evotaz are its ability to provide sustainable virological suppression if given as part of combination with other antiretroviral medicinal products for treatment of HIV-1 infection. The most frequently reported adverse reactions were ocular icterus, nausea and jaundice.

The full indication is: "Evotaz is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir (see sections 4.4 and 5.1)". It is proposed that Evotaz be prescribed by physicians experienced in the treatment of a physician 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 made available in all official European Union languages after 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 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact