



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2010
EMA/CHMP/258896/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (post authorisation)

Reyataz

Atazanavir sulphate

On 22 April 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 Reyataz. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG. 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 new indication* as follows:

“REYATAZ capsules, co-administered with low dose ritonavir, are indicated for the treatment of HIV 1 infected adults and paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products.

Based on available virological and clinical data from adult patients, no benefit is expected in patients with strains resistant to multiple protease inhibitors (≥ 4 PI mutations). There are very limited data available from children aged 6 to less than 18 years (see sections 4.4 and 5.1).

The choice of REYATAZ in treatment experienced adult and paediatric patients should be based on individual viral resistance testing and the patient's treatment history (see sections 4.4 and 5.1).”

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.

