



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
REYATAZ

International Nonproprietary Name (INN): *atazanavir sulphate*

On 24 April 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the 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.

The CHMP adopted a new indication as follows:

Antiretroviral treatment naïve patients.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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 indication for Reyataz will be as follows***:

Reyataz is indicated for the treatment of HIV-1 infected adults in combination with other antiretroviral medicinal products.

In antiretroviral treatment experienced patients, the demonstration of efficacy is based on a study comparing Reyataz 300 mg once daily in combination with ritonavir 100 mg once daily with lopinavir/ritonavir, each regimen in combination with tenofovir (see sections 4.8 and 5.1). Based on available virological and clinical data, no benefit is expected in patients with strains resistant to multiple protease inhibitors (≥ 4 PI mutations). The choice of Reyataz **in treatment experienced patients** should be based on individual viral resistance testing and the patient's treatment history (see section 5.1).

* 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.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.