



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 April 2016  
EMA/CHMP/265549/2016  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Reyataz

atazanavir / atazanavir sulfate

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change 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 change to the existing indication as follows<sup>2</sup>:

“REYATAZ oral powder, co-administered with low dose ritonavir, is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients at least 3 months of age and weighing at least 5 kg (see section 4.2).

Based on available virological and clinical data from adult patients, no benefit is expected in patients with strains resistant to multiple protease inhibitors ( $\geq 4$  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).”

In addition, Reyataz will also be available as an oral powder.

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> **New text in bold, removed text as strikethrough**

