23 June 2016
EMA/CHMP/258309/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Atazanavir Mylan

atazanavir

On 23 June 2016 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Atazanavir Mylan, intended for the treatment of HIV-1 infection in adults and children 6 years of age and older. The applicant for this medicinal product is Mylan S.A.S.

Atazanavir Mylan will be available as hard capsules (150 mg, 200 mg and 300 mg). The active substance of Atazanavir Mylan is atazanavir, an antiviral for systemic use for the treatment of HIV infection (ATC code: J05AE08). Atazanavir is an inhibitor of the viral protease enzyme which is key for viral replication.

Atazanavir Mylan is a generic of Reyataz, which has been authorised in the EU since 2 March 2004. Studies have demonstrated the satisfactory quality of Atazanavir Mylan, and its bioequivalence to the reference product Reyataz. A question and answer document on generic medicines can be found here.

The full indication is:

> "Atazanavir Mylan, co-administered with low dose ritonavir, is 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 Atazanavir Mylan 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)".

It is proposed that Atazanavir Mylan be prescribed by physicians 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

[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

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.