EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2017
EMA/292939/2017
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): atazanavir / cobicistat

Procedure No. EMEA/H/C/PSUSA/00010404/201607

Period covered by the PSUR: 14 January 2016 - 28 July 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for atazanavir / cobicistat, the scientific conclusions of CHMP are as follows:

During the reporting period of this Period Safety Updated Report (PSUR), data on atazanavir excretion in human milk has become available. So far it was only known that in rats, atazanavir (ATV) was excreted in milk.

The data now available concerns a study in postpartum mothers receiving highly active antiretroviral therapy (HAART) for HIV investigated mother-to-child transmission of HIV through breast feeding. Atazanavir was detected in the breast milk of subjects receiving ATV (n = 3) by a validated assay. The variability of the ATV values in milk is important, ranging from 21 to 827 ng/ml at Day 5 post-partum and from 60 to 1502 ng/ml at Day 14 post-partum. The median breast milk/plasma ratio was 0.13. There are no additional information about the 3 women (e.g. composition of the ARV regimen; HIV RNA levels; safety data). No other literature data on the PK of ATV in human milk was retrieved.

Therefore, in view of the data presented in the reported period reviewed in this PSUR(s), the PRAC considered that changes to the product information were warranted to reflect that atazanavir can be found in human milk.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for atazanavir / cobicistat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing atazanavir / cobicistat is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.