EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): adefovir

Procedure No. EMEA/H/C/PSUSA/00000060/201809

Period covered by the PSUR: 21 September 2015 to 20 September 2018

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Scientific conclusions

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

Based on a PRAC request, the MAH has reconsidered the frequency categories of Fanconi syndrome and proximal renal tubulopathy in the SmPC for Hepsera. The safety data derived from 5 pivotal randomized controlled studies, including a total of 1,174 patients, were reviewed. On the basis of an algorithm defining possible proximal renal tubulopathy and/or Fanconi syndrome as confirmed abnormalities, 28 cases of proximal renal tubulopathy (including possible Fanconi syndrome) were retrieved in the clinical safety dataset. After reviewing the description of the cases, 5 cases of possible proximal renal tubulopathy and/or Fanconi syndrome were sufficiently well documented with no alternative aetiology and/or having a temporal association with Hepsera treatment. On the basis of these data, the frequency of these adverse drug reactions is calculated to be 0.4% corresponding to the frequency category uncommon. As a result, the frequency category of proximal renal tubulopathy and Fanconi syndrome is revised from unknown to uncommon in section 4.8 of Hepsera SmPC and in the corresponding section of the package leaflet. Moreover, to emphasize that the frequency is more driven by the more common event proximal renal tubulopathy, the terms are combined as follows “Proximal renal tubulopathy (including Fanconi syndrome)” rather the two terms separated.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for adefovir the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing adefovir 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.