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EMA/CHMP/753938/2014
Committee for Medicinal Products for Human Use (CHMP)

Aclasta

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: ZOLEDRONIC ACID

Procedure No. EMEA/H/C/000595/PSUV/0047

Period covered by the PSUR: 1 May 2012 – 31 August 2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Aclasta, the scientific conclusions of PRAC are as follows:

Based on recent publications which demonstrate that anti-angiogenic medicinal products are associated with ONJ, the MAH proposed additions of “anti-angiogenic medicinal products” to the existing concomitant risk factors in sections 4.4 and 4.8 of the Aclasta SmPC are endorsed.

As the up-to date cumulative MAH safety database review retrieved a total of 280 reported cases of Osteonecrosis of the jaw (ONJ), the PRAC recommends to amend the information in the SmPC as the current wording focuses mainly on cancer patients. A statement that “Osteonecrosis of the jaw has been reported in patients treated with zoledronic acid” is added in section 4.4. Specific information of ONJ in patients with cancer-indication (with different dosing regimen) that is currently repetitious in both 4.4 and 4.8 should be deleted in section 4.4, but can be maintained in section 4.8 (description of selected adverse reactions).

The PRAC recommended to change (placement of) information on hydration and calcium intake, currently presented in SmPC section 4.2 under the subheading on Paget`s disease, as hydration intake and calcium intake are important for all patients treated with Aclasta.

Therefore, and in view of available data regarding ONJ, the PRAC considered that changes to the product information were warranted for zoledronic acid 5mg (Aclasta indications)

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Aclasta, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance ZOLEDRONIC ACID 5mg is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.