25 February 2016
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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): ibandronic acid, sodium ibandronate

Procedure No. EMEA/H/C/PSUSA/00001702/201506

Period covered by the PSUR: 25 June 2012 - 24 June 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ibandronic acid, sodium ibandronate, the scientific conclusions of CHMP are as follows:

It is recommended that the product information (SmPC and PL) for all formulations is revised to reflect the current knowledge on Osteonecrosis of the jaw (ONJ) and to optimize risk minimisation.

In addition, although the risk for ONJ may be well known for the prescribers, further awareness on such risk is needed for the patients. Thus, it is considered warranted to implement a patient reminder card for parenteral formulations as an additional risk minimisation measure for ONJ. These changes are suggested following conclusions by the PRAC upon review of zoledronic acid PSUR. The PRAC concluded that the risk of osteonecrosis (or death of bone tissue) in the jaw remains very low, but has recommended a number of measures to minimise the risk. It was also decided to introduce to ibandronic acid the same measures taken for other bisphosphonates and denosumab. The aim is to implement similar wording across all products concerned to optimize risk minimisation and ensure consistency in information provided to patients.

In spite of the absence of significant new information reported in this PSUR regarding ONJ, it is suggested that the MAH implements the SmPC, Annex II and PL updates and the patient reminder card with relation to ONJ in order to optimize risk minimisation, as it is considered class information.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the PI of medicinal products containing ibandronic acid were warranted.

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 ibandronic acid, sodium ibandronate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ibandronic acid, sodium ibandronate 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.

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