EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: zoledronic acid (indicated for Osteoporosis)

Procedure No. EMEA/H/C/PSUSA/00009334/201408

Period covered by the PSUR: 01 September 2013 – 31 August 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for zoledronic acid (indicated for Osteoporosis), the scientific conclusions of CHMP are as follows:

With regards to the risk of Osteonecrosis of the jaw (ONJ), it is recommended that the product information is revised to reflect the current knowledge on 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 as part of the existing patient information pack, as an additional risk minimisation measure for ONJ. The wording for the reminder card has been agreed by the PRAC.

Therefore, in view of available data regarding zoledronic acid (indicated for Osteoporosis), the PRAC considered that changes to the product information and conditions of the marketing authorisation were warranted.

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 zoledronic acid (indicated for Osteoporosis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing zoledronic acid (indicated for Osteoporosis) is favourable subject to the proposed changes to the product information

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