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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): zoledronic acid (indicated for cancer and fractures)

Procedure No. EMEA/H/C/PSUSA/00003149/201508

Period covered by the PSUR: 1 September 2014 – 31 August 2015

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Scientific conclusions

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

Following assessment of this PSUR (reporting period 01 September 2014 –31 August 2015) the PRAC concluded that Acquired Fanconi syndrome (FS) should be included in the section 4.8 of the SmPC with the frequency 'rare'. This recommendation is following the identification of two serious adverse events (SAE's) of Acquired FS from clinical trials which indicates that the frequency of such events is 0.01 % which in the corresponding frequency category based on the CIOMS III convention is considered as 'rare' (>1/10,000, <1/1,000).

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing zoledronic acid (indicated for cancer and fractures) 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 zoledronic acid (indicated for cancer and fractures) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing zoledronic acid (indicated for cancer and fractures) 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.