25 April 2024
EMA/113943/2026
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/00003149/202308

Period covered by the PSUR:
01/09/2020 To: 31/08/2023

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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 PRAC are as follows:

In view of available data on tubulointerstitial nephritis from the literature, spontaneous reports including in some cases a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC is of the view that a causal relationship between zoledronic acid (indicated for cancer and fractures) and tubulointerstitial nephritis is at least a reasonable possibility. The PRAC concluded that the product information of products containing zoledronic acid (indicated for cancer and fractures) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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.