EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
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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

Procedure No.: EMEA/H/C/PSUSA/00001702/202106

Period covered by the PSUR: 25/06/2018 To: 24/06/2021

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Scientific conclusions

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

In view of available data on hypocalcaemia from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and the fact that hypocalcaemia is an identified risk for ibandronic acid, the PRAC considers that a causal relationship between ibandronic acid and hypocalcaemia is established. The PRAC concluded that the product information of products containing ibandronic acid (osteoporotic indication (Bonviva)) should be amended accordingly.

Update of section 4.8 of the SmPC to add the ADR hypocalcaemia with a frequency uncommon. The Package leaflet is updated accordingly.

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.