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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): radium-223 dichloride

Procedure No. EMEA/H/C/PSUSA/00010132/201611

Period covered by the PSUR: 15 May 2016 to 14 November 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for radium-223 dichloride, the scientific conclusions of CHMP are as follows:

The MAH has provided an extensive review of the data from clinical trials and post-marketing settings regarding the possible role of Xofigo in dehydration. Although the data are not supportive of a direct causal correlation, the relationship between potential dehydration and prolonged bouts of vomiting and diarrhoea is well characterised. Based on this outcome, section 4.4 of the SmPC is updated with precautionary wording regarding the risk of dehydration.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC Rapporteur considered that changes to the product information of medicinal products containing Radium-223 dichloride 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 radium-223 dichloride the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing radium-223 dichloride 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.