15 December 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): pemigatinib

Procedure No. EMEA/H/C/PSUSA/00010923/202204

Period covered by the PSUR: 16 October 2021 – 16 April 2022

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Scientific conclusions

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

In view of available data on prolonged hyperphosphatemia that can cause precipitation of calcium-phosphate crystals and lead to non-uraemic calciphylaxis as reported in 4 spontaneous case reports including in one case with a close temporal relationship, in view of the known relationship of non-uraemic calciphylaxis and hyperphosphatemia described in the literature, and a plausible mechanism of action, the PRAC considers a relationship between pemigatinib and non-uraemic calciphylaxis is a possibility and HCPs should be aware of this in the context of soft tissue mineralization. The PRAC concluded that the product information of products containing pemigatinib should be amended 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 pemigatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pemigatinib 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.