25 May 2023
EMA/366120/2023
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/00010923/202210

Period covered by the PSUR: 17 April 2022 – 16 October 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 cutaneous calcification from clinical trials, including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pemigatinib and cutaneous calcification is at least a reasonable possibility. 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.