EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): fostamatinib

Procedure No. EMEA/H/C/PSUSA/00010819/202010

Period covered by the PSUR: 16 April 2020 – 16 October 2020

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Scientific conclusions

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

Based on the PSUR data submitted and the relatively high number (59x) of cases reporting headache, including 16 cases with a clear temporal relationship, and a case with a positive rechallenge, the PRAC concluded that product information should be amended by including 'headache' as an ADR with frequency "common".

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 fostamatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fostamatinib 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.