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): bromfenac

Procedure No. PSUSA/00000436/202505

Period covered by the PSUR:
2 years to 30 May 2025

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Scientific conclusions

Considering the PRAC Assessment Report on the PSUR(s) for bromfenac, the scientific conclusions of the PRAC are as follows:

In view of available data on risks when used during pregnancy, from the literature and spontaneous reports within the same class, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bromfenac and risks with use during pregnancy is at least a reasonable possibility. The PRAC concluded that the product information of products containing bromfenac should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for bromfenac the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bromfenac 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.