



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2023
EMA/192804/2023
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): bupivacaine/meloxicam

Procedure No. EMEA/H/C/PSUSA/00010880/202209

Period covered by the PSUR: 24 March 2022 to 23 September 2022



Scientific conclusions

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

In view of available data about the use of bupivacaine / meloxicam during lactation, based on the results of study HTX-011-220 (showing that bupivacaine / meloxicam is excreted in breastmilk for 6-8 days), and information about use during pregnancy, based on the PRAC advice for NSAID-containing medicinal products (EMA/CMDh/642745/2022), the PRAC considers that the product information should be strengthened 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 bupivacaine/meloxicam the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bupivacaine/meloxicam 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.