25 June 2026
EMADOC-1700519818-3435345
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): methotrexate

Procedure No. PSUSA/00002014/202510

Period covered by the PSUR: 2 years to 31 October 2025

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Scientific conclusions

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

In view of available data on epidermal necrosis from the literature and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between methotrexate and epidermal necrosis is at least a reasonable possibility. The PRAC concluded that the product information of products containing methotrexate 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 methotrexate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing methotrexate 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.