27 June 2024
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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): methotrexate

Procedure No. EMEA/H/C/PSUSA/00002014/202310

Period covered by the PSUR: 01/11/2021 To: 31/10/2023

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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 photosensitivity reactions from spontaneous cases including one fatal case and literature, the PRAC considers that the adverse drug reaction on photosensitivity reactions should be added or revised and that a warning on the risk of photosensitivity should be implemented in the product information of products containing methotrexate.

In view of available data on a drug interaction between methotrexate and metamizole from spontaneous reports and literature, the PRAC considers that concurrent use of methotrexate and metamizole can increase haematotoxicity, especially in elderly patients.

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.