



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): hydroxycarbamide (for centrally authorised product only)

Procedure No. PSUSA/00001692/202506

Period covered by the PSUR: 29 June 2024 to 28 June 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for hydroxycarbamide (for centrally authorised product only), the scientific conclusions of PRAC are as follows:

In view of available data on limbal stem cell deficiency risk from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between hydroxycarbamide and limbal stem cell deficiency is at least a reasonable possibility. The PRAC concluded that the product information of products containing hydroxycarbamide 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 hydroxycarbamide (for centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing hydroxycarbamide (for centrally authorised product only) 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.