30 January 2025
EMA/22154/2025
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. EMEA/H/C/PSUSA/00001692/202406

Period covered by the PSUR: 28/06/2023 To: 28/06/2024

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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 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 Rapporteur considers a causal relationship between Hydroxycarbamide and the risk of "Interference with Continuous Glucose Monitoring systems" is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of XROMI 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.