17 October 2024
EMA/551566/2024
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): agomelatine

Procedure No. EMEA/H/C/PSUSA/00000071/202402

Period covered by the PSUR: 20 February 2021 To: 19 February 2024

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Scientific conclusions

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

In view of the measures to avoid hepatotoxicity implemented in clinical guidelines/practice and adequately described in the SmPC and PL and in view of the contraindication to potent CYP1A2-inhibitors adequately stated in the SmPC and PL, and cases of contraindication declining, the PRAC agreed that the additional risk minimisation measures can be deleted from the Annex II.D and RMP.

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 agomelatine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing agomelatine 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.