25 April 2025
DOC_REF_ID
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): naltrexone / bupropion

Procedure No. EMEA/H/C/PSUSA/00010366/202409

Period covered by the PSUR: 09/09/2023 To: 09/09/2024

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Scientific conclusions

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

In view of available data on the risk of inadequate analgesia caused by interactions with opioids from spontaneous reports, as well as the requirements of GVP Module XVI (Rev 3), the PRAC concluded that the product information of products containing naltrexone/bupropion should be amended to include a statement on the availability and accessibility of the patient card for Mysimba.

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