



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2022
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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): naltrexone / bupropion

Procedure No. EMEA/H/C/PSUSA/00010366/202109

Period covered by the PSUR: 09 September 2020 - 09 September 2021



Scientific conclusions

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

In view of available data on the risk of panic attacks from a clinical trial and spontaneous reports, the PRAC considers that a causal relationship between naltrexone/bupropion and panic attacks is at least a reasonable possibility.

The PRAC concluded that the product information of products containing naltrexone/bupropion should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.