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): naltrexone / bupropion

Procedure No. EMEA/H/C/PSUSA/00010366/201609

Period covered by the PSUR: 27-Mar-2016 to 26-Sep-2016

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Scientific conclusions

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

Based on a review of the clinical trials and post-marketing reports of serious and non-serious cases hepatotoxicity, there is evidence to suggest a possible causal relationship between hepatotoxicity and the use of the combination product naltrexone/bupropion. Non-serious cases were reported resulting in an elevation of liver enzymes. In addition, drug-induced liver injury (DILI) has been described in clinical trials.

With regard to suicidal behaviour, a review of post-marketing events has revealed that the suicidality events does not predominantly concern younger patients below the age of 25 years but patients above the age of 40 years.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing the combination product naltrexone / bupropion were warranted.

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 products containing naltrexone/bupropion is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.