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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/00010366/202009

Period covered by the PSUR: 9 September 2019 to 9 September 2020

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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 from cumulative reviews, including cases with a reasonable temporal relationship and in view of a plausible mechanism of pharmacokinetic interaction with serotonergic agents, the PRAC considers a causal relationship between administration of naltrexone/bupropion and serotonin syndrome is at least a reasonable possibility.

In addition, based on data from cumulative reviews, including in some cases a close temporal relationship, the PRAC considers that there is at least a reasonable possibility for a causal association between administration of naltrexone/bupropion and hypertensive crisis.

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.