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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/00010366/202209

Period covered by the PSUR: 09/09/2021 - 09/09/2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 acute generalised exanthematous pustulosis (AGEP), including four cases with a close temporal relationship and supported by data for the mono-substance bupropion, the PRAC considers that a causal relationship between naltrexone/bupropion and AGEP 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.