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/00010366/201709

Period covered by the PSUR: 10 March to 9 September 2017

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Scientific conclusions and grounds for variation to the terms of the marketing authorisations

Based on cases of urticaria from clinical trials and spontaneous reporting related to the treatment with naltrexone/bupropion, the SmPC should be updated to reflect that urticaria is not only an adverse reaction of bupropion but also of the naltrexone/bupropion combination. Based on integrated clinical trial data, the frequency of urticaria is uncommon for the treatment with naltrexone/bupropion.

The Package Leaflet (PL) does not have to be changed because it already includes urticaria listed as hives with frequency common in section 4. In general, only the highest frequency category for an adverse reaction is included in the PL as adverse reactions are not grouped by the suspected active substance.