12 October 2017
EMA/73378/2018
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/00010366/201703

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During this review swellings in the facial area have been determined as expressions of an angioedema and as a consequence “angioedema” should be included in the SmPC as ADR of the combination naltrexone / bupropion and not only of the mono-component bupropion. There are a total of 10 cases of symptoms resembling angioedema with a reasonable assumption of a causal relationship to treatment. Therefore, the product information should be changed in a way, that angioedema is associated with the combination and not only with the mono-products.