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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): pregabalin

Procedure No. EMEA/H/C/PSUSA/00002511/202001

Period covered by the PSUR: From: 01/02/2019 To: 31/01/2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for pregabalin, the scientific conclusions of CHMP are as follows:

In view of available data on risk of respiratory depression from spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pregabalin and respiratory depression is established and concluded that the product information of products containing pregabalin should be amended accordingly.

Update of section 4.4 of the SmPC to add a warning regarding respiratory depression related to pregabalin in patients without concomitant use of opioids and/or other CNS depressants and without risk factors as well in the setting of risk factors such as underlying respiratory impairment and/or use of CNS depressants.

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 pregabalin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pregabalin 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.