



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/598198/2021
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/00002511/202101

Period covered by the PSUR: 01 February 2020 To: 31 January 2021



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 drug-induced parkinsonism from spontaneous reports including literature case reports and in view of availability of a possible mechanism of action, the PRAC considers a causal relationship between pregabalin and Parkinsonism is established and concluded that the product information of products containing pregabalin 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 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.