



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2021
EMA/256140/2021
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): perampanel

Procedure No. EMEA/H/C/PSUSA/00009255/202007

Period covered by the PSUR: 21 July 2019 to 21 July 2020



Scientific conclusions

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

In view of available data on coma and depressed level of consciousness from spontaneous reports including 3 relevant cases of coma and 7 relevant cases of depressed level of consciousness, all with a close temporal relationship and a positive de-challenge, the PRAC considers that a causal relationship between perampanel and coma / depressed level of consciousness is at least a reasonable possibility. The PRAC concluded that the product information of products containing perampanel 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 perampanel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing perampanel 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.