EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
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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): perampanel

Procedure No. EMEA/H/C/PSUSA/00009255/202107

Period covered by the PSUR: 22 July 2020 To: 22 July 2021

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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 hallucinations from spontaneous reports, clinical trials and literature, including 20 cases possibly related and 5 cases probably related to perampanel (including 2 cases in which hallucinations occurred from 15 to 60 min following perampanel intake), with a compatible temporal relationship and mainly with a positive dechallenge, the PRAC considers a causal relationship between perampanel and hallucinations 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.