



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2023
EMA/151418/2023
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/00009255/202207

Period covered by the PSUR: 21/07/2021 To: 21/07/2022



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 the 18 cases of psychotic disorders from clinical trials including 10 cases with positive dechallenge, the literature (2 case reports), spontaneous reports including in 10 cases a close temporal relationship, a positive dechallenge in 6 cases and rechallenge in 1 case, the PRAC considers a causal relationship between perampanel and psychotic disorder 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.