EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2026
EMADOC-1700519818-3024888
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. PSUSA/00009255/202507

Period covered by the PSUR:
3 years to 22 July 2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of spontaneous and literature cases of overdose, a causal relationship between perampanel and vomiting in overdose context is considered at least a reasonable possibility. The product information of products containing perampanel should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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.