



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 November 2023  
EMA/505768/2023  
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): cenobamate

Procedure No. EMEA/H/C/PSUSA/00010921/202303

Period covered by the PSUR: 19/05/2022 To: 26/03/2023



## **Scientific conclusions**

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

In view of available data from clinical trials and spontaneous reports, including 11 Individual Case Safety Reports with a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between cenobamate and "suicidal ideation" is at least a reasonable possibility. The PRAC concluded that the product information of products containing cenobamate 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 cenobamate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cenobamate 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.