



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2020
EMA/654572/2020
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): brivaracetam

Procedure No. EMEA/H/C/PSUSA/00010447/202001

Period covered by the PSUR: 15/01/2019 To: 14/01/2020



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for brivaracetam, the scientific conclusions of CHMP are as follows:

A case series of five patients reported major increases in brivaracetam plasma levels (by 95% to 280%) during introduction of adjunctive cannabidiol therapy. The mechanism of interaction is not clear, but possibly through CYP2C19 inhibition. The clinical relevance of the interaction is uncertain. In view of these data, the PRAC agrees that the information should be reflected in the section 4.5 of the SmPC. 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 brivaracetam the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing brivaracetam 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.