



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/154379/2025
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): opicapone

Procedure No. EMEA/H/C/PSUSA/00010516/202406

Period covered by the PSUR: 23 June 2021 To: 23 June 2024



Scientific conclusions

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

In view of available data on confusional state from clinical trials, spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considered that a causal relationship between opicapone and confusional state is at least a reasonable possibility. The PRAC concluded that the product information of products containing opicapone 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 opicapone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing opicapone 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.