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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): levetiracetam

Procedure No. PSUSA/00001846/202411

Period covered by the PSUR: 3 years to 30 November 2024

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Scientific conclusions

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

In view of the available data from the observational population-based registry studies with more recent information on the risk of neurodevelopmental disorders in children exposed prenatally to levetiracetam, the PRAC concluded that the product information of products containing levetiracetam 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 levetiracetam the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing levetiracetam 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.