17 October 2024
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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): rivastigmine

Procedure No. EMEA/H/C/PSUSA/00002654/202401

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Scientific conclusions

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

Based on literature data suggestive of a causal relationship between rivastigmine and pleurothotonus reporting either positive dechallenge and/or rechallenge, including a dose-effect relationship in some cases and in view of a potential class effect, it is recommended to amend the product information of rivastigmine containing products accordingly to include the adverse reaction 'pleurothotonus' also known as Pisa syndrome.

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 rivastigmine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rivastigmine 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.