EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2020
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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): zonisamide

Procedure No. EMEA/H/C/PSUSA/00003152/202003

Period covered by the PSUR: 30 March 2019 to 30 March 2020

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Scientific conclusions

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

In view of available data on hyperammonaemia from the literature and spontaneous reports, including in some cases a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between zonisamide and hyperammonaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing zonisamide should be amended accordingly.

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