14 November 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): siponimod

Procedure No. EMEA/H/C/PSUSA/00010818/202403

Period covered by the PSUR: 26 March 2023 To: 25 March 2024

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Scientific conclusions

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

In view of available data on IRIS syndrome and melanoma from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between Siponimod and IRIS and melanoma is at least a reasonable possibility. The PRAC concluded that the product information of products containing siponimod 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 siponimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing siponimod 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.