EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00010818/202003

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Scientific conclusions

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

Given the Basal Cell Carcinoma siponimod data and background data, there is evidence for an increase in the risk of BCC with siponimod. The underlying mechanism is unknown, but a hypothetical mechanism related to systemic immunosuppression and reduced immune-surveillance for increased risk of BCC in patients treated with siponimod has been suggested. The Product Information should be varied 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 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.