10 November 2022
EMA/856981/2022
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/00010818/202203

Period covered by the PSUR: 26 September 2021 To: 25 March 2022

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Scientific conclusions

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

In view of available data on lymphopenia from spontaneous reports and in view of a plausible mechanism of action, the PRAC concluded that the product information of products containing siponimod should be amended accordingly in order to ensure a better monitoring of lymphopenia and align the recommendations with the product information of fingolimod.

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.