



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/134330/2025
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): efgartigimod alfa

Procedure No. EMEA/H/C/PSUSA/00011014/202406

Period covered by the PSUR: 16 December 2023 To: 16 June 2024



Scientific conclusions

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

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