20 July 2023
EMA/449300/2023
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/00011014/202212

Period covered by the PSUR: 16 June 2022 To: 16 December 2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2023. Reproduction is authorised provided the source is acknowledged.

Scientific conclusions

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

In view of available data on anaphylactic reactions consisting of spontaneous reports, including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between efgartigimod alfa and anaphylactic reaction is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing efgartigimod alfa 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 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.