9 November 2023
EMA/263695/2024
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): eftrenonacog alfa

Procedure No. EMEA/H/C/PSUSA/00010499/202303

Period covered by the PSUR:
20/03/2020 To: 19/03/2023

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**Scientific conclusions**

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

In view of available data on risks from spontaneous reports, including in most cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between eftrenonacog alfa and **anaphylactic shock**. Currently only "Anaphylactic Reaction" is listed in the summary of product characteristics. Since "Anaphylactic Shock" is more severe than anaphylactic reaction it should be captured separately.

The PRAC concluded that the product information of products containing eftrenonacog alfa should be amended accordingly.

**Summary of Product Characteristics**

- Section 4.8

The following adverse reaction should be added under the SOC Immune system disorders with a frequency not known: **Anaphylactic shock**

**Package Leaflet**

- **Section 4 Possible side effects**

**Side effects with frequency not known (frequency cannot be estimated from the available data): sudden, severe allergic reaction and life-threatening allergic reaction (anaphylactic shock).**

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 eftrenonacog alfa the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing eftrenonacog 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.

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