EMA/492734/2018
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/00010499/201803

Period covered by the PSUR: 20 September 2017 - 19 March 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Following evaluation of the available evidence, the marketing authorisation holder confirmed the signal on hypersensitivity and consequently updated sections 4.4 and 4.8 of the SmPC. Hypersensitivity is a well-known adverse reaction in context with coagulation factor treatment with anaphylaxis representing the most severe form of a hypersensitivity reaction.

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 eftrenonacog alfa the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) 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.