EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): cerliponase alfa

Procedure No. EMEA/H/C/PSUSA/00010596/201904

Period covered by the PSUR: 27/10/2018 To: 26/04/2019

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Scientific conclusions

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

Information on anaphylaxis has been included in the SmPC, based on two reports that occurred during the reporting period; one spontaneous case and one clinical trial case. 'Anaphylactic reaction' is to be included in section 4.8 with the frequency 'common' and section 4.4 is to be revised regarding information on 'anaphylactic reactions'.

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