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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): alglucosidase alfa

Procedure No. EMEA/H/C/PSUSA/00000086/201609

Period covered by the PSUR: 29 September 2013 – 28 September 2016

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Scientific conclusions

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

- Considering the information provided on the reported consequences related to extravasation of alglucosidase alfa, PRAC considered that update of the product information was warranted with inclusion of the adverse reactions infusion site swelling, infusion site induration and infusion site extravasation with a frequency not known.

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