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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/00000086/202109

Period covered by the PSUR: 28/09/2019 To: 28/09/2021

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Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

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

In view of available data on infusion associated reactions from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between algucosidase alfa and the following adverse drug reactions: dyspepsia, dysphagia, transient skin discoloration, blister, palmar erythema, infusion site erythema, infusion site urticaria, and hypoxia, is at least a reasonable possibility. The PRAC concluded that the product information of products containing alglucosidase 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 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.