EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: pegloticase

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for pegloticase, the scientific conclusions of CHMP are as follows:

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

Reports of infusion related reactions or anaphylaxis coincident with concomitant use of oral urate lowering agents were submitted in this Periodic Safety Update Report, where infusion reactions in 28 cases and 9 cases with anaphylactic reactions were reported. As the development of these adverse events may have been prevented in at least some of these cases if the patients would not have been treated with concomitant urate lowering substances, an amendment of the summary of product characteristics focusing on the importance of stopping treatment with uric acid lowering agents with regard to masking the results of serum uric acid values (and therefore increasing the risk for infusion reactions and anaphylactic reactions) should be implemented. The revised order of the two corresponding paragraphs is to emphasize the correlation between concomitant medication with urate lowering products and serum uric acid measurement. In addition, a further amendment regarding the extension of the time of observation following the end of infusion from 1 hour to 2 hours as a precautionary measure has been included along with a statement that delayed-type hypersensitivity reactions have also been reported.

Therefore, in view of available data regarding anaphylaxis and infusion reactions, the Pharmacovigilance Risk Assessment Committee considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for pegloticase the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing pegloticase is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.