24 July 2025
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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): pegzilarginase

Procedure No. PSUSA/00000222/202412

Period covered by the PSUR:
6 months to 13 December 2024

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Scientific conclusions

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

In view of available data on hypersensitivity from the active surveillance programme including two cases of hypersensitivity after subcutaneous administration, one of them severe, in a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers an amendment of the concerned sections of the product information of medicinal products containing pegzilarginase necessary.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for pegzilarginase the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pegzilarginase 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.