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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): etelcalcetide

Procedure No. EMEA/H/C/PSUSA/00010533/201711

Period covered by the PSUR: 11/05/2017 - 10/11/2017

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Scientific conclusions

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

A cumulative review of data from post-marketing sources (as of 10 November 2017) identified a total of 55 hypersensitivity and infusion-site reactions. Of these, seven cases were serious, including one case with a fatal outcome. In two of the serious cases, the anaphylactic reaction and face swelling occurred after administration of the first dose of etelcalcetide. Based on the available data and considering that the active substance is a peptide, the causal relationship between the hypersensitivity reactions and etelcalcetide was considered likely.

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