EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): degarelix

Procedure No. EMEA/H/C/PSUSA/00000944/201902

Period covered by the PSUR: from 17 February 2016 to 17 February 2019

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Scientific conclusions

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

8 cases of rhabdomyolysis have cumulativly been reported with degarelix. In 4 of the 8 cases, the causal relationship between degarelix and the event could not be ruled out; the cases were well documented, without evident alternative aetiology or confounding factors, with compatible time-to-onset and positive dechallenge and increased blood CPK. In each case degarelix was discontinued. In conclusion, rhabdomyolysis should be added to the list of ADRs of the Product Information with a frequency rare.

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