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EMA/CHMP/29520/2015
Committee for Medicinal Products for Human Use (CHMP)

Firmagon

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

International non-proprietary name: degarelix

Procedure No. EMEA/H/C/000986/PSUV/0023

Period covered by the PSUR: 18 February 2013 17 February 2014

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Scientific conclusions

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

Nine cases of inappropriate schedule of drug administration were reported cumulatively with degarelix. In order to avoid inappropriate schedule of drug administration, section 4.2 of the SmPC and package leaflet should be revised to clarify that both subcutaneous injections of 120 mg each have to be administered consecutively.

Therefore, in view of available data regarding degarelix, the PRAC 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 Firmagon, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance DEGARELIX is favourable subject to the proposed changes to the product information.

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