16 September 2021
EMA/CHMP/498649/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Firmagon

degarelix

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Firmagon. The marketing authorisation holder for this medicinal product is Ferring Pharmaceuticals A/S.

The CHMP adopted an extension to the existing indication as follows:[2]

Firmagon is a gonadotrophin releasing hormone (GnRH) antagonist indicated:

- **for treatment of high-risk localized and locally advanced hormone-dependent prostate cancer in combination with radiotherapy.**
- **as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone-dependent prostate cancer.**
- for treatment of adult male patients with advanced hormone-dependent prostate cancer.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text **in bold**

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