EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2023
EMA/CHMP/325725/2023
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Degarelix Accord

degarelix acetate

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Degarelix Accord, intended for the treatment of hormone dependent prostate cancer. The applicant for this medicinal product is Accord Healthcare S.L.U.

Degarelix Accord will be available as an 80 mg and 120 mg powder and solvent for solution for injection. The active substance of Degarelix Accord is degarelix acetate, a gonadotropin-releasing hormone receptor antagonist (ATC code: L02BX02). Degarelix binds to receptors in the pituitary gland resulting in decreased secretion of luteinizing hormone and follicle-stimulating hormone, thereby reducing the secretion of testosterone by the testes, which slows down the growth of prostate cancer cells.

Degarelix Accord is a generic of Firmagon which has been authorised in the EU since 17 February 2009. Studies have demonstrated the satisfactory quality of Degarelix Accord, and its bioequivalence to the reference product Firmagon. A bioequivalence study versus the reference product Firmagon was not required because of the qualitative and quantitative compositions and the nature and behaviour of the products. A question and answer document on generic medicines can be found here.

The full indication is:

Degarelix Accord is a gonadotrophin releasing hormone (GnRH) antagonist indicated:

- for treatment of adult male patients with advanced hormone-dependent prostate cancer.
- for treatment of high-risk localised 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

Detailed recommendations for the use of this product will be described in the summary of product

[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

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.