19 May 2022
EMA/CHMP/254792/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ganirelix Gedeon Richter

ganirelix

On 19 May 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ganirelix Gedeon Richter, intended for the prevention of premature ovulation in women receiving fertility treatment and who are having ovarian stimulation. The applicant for this medicinal product is Gedeon Richter Plc.

Ganirelix Gedeon Richter will be available as a 0.25 mg/0.5 mL solution for injection. The active substance of Ganirelix Gedeon Richter is ganirelix, an anti-gonadotropin-releasing hormone (ATC code: H01CC01) which reversibly suppresses the release of endogenous gonadotropins to prevent premature ovulation.

Ganirelix Gedeon Richter is a generic of Orgalutran, which has been authorised in the EU since 16 May 2000. Studies have demonstrated the satisfactory quality of Ganirelix Gedeon Richter. Since Ganirelix Gedeon Richter is administered subcutaneously, and contains the same active substance in the same concentration and the same excipients in similar concentrations compared with the reference product, a bioequivalence study versus the reference product Orgalutran was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Ganirelix Gedeon Richter is indicated for the prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART).
>
> In clinical studies ganirelix was used with recombinant human follicle stimulating hormone (FSH) or corifollitropin alfa, the sustained follicle stimulant.

Ganirelix Gedeon Richter should be prescribed by physicians experienced in the treatment of infertility.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.