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Ganirelix Gedeon Richter (*ganirelix*)

An overview of Ganirelix Gedeon Richter and why it is authorised in the EU

What is Ganirelix Gedeon Richter and what is it used for?

Ganirelix Gedeon Richter is a medicine used to prevent premature ovulation (early release of eggs from the ovary) in women having fertility treatment and who are having ovarian stimulation (stimulation of the ovaries so that they produce more eggs).

Ganirelix Gedeon Richter contains the active substance ganirelix and is a 'generic medicine'. This means that the medicine contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Orgalutran. For more information on generic medicines, see the question-and-answer document here.

How is Ganirelix Gedeon Richter used?

Ganirelix Gedeon Richter can only be obtained with a prescription and should only be prescribed by a doctor experienced in the treatment of infertility.

Ganirelix Gedeon Richter is available in prefilled syringes as a solution for injection. The injection is given once a day under the skin and treatment should start on day 5 or 6 after the start of ovarian stimulation with follicle-stimulating hormone (FSH) or corifollitropin alfa (a modified FSH). When treatment should start depends on how well the ovaries are responding to stimulation. Treatment with Ganirelix Gedeon Richter should be continued up to the day that there are enough large follicles (small sacs in the ovary that hold the eggs) to allow egg collection (harvesting).

Ganirelix Gedeon Richter is preferably given into the upper leg. The patient or their partner may give the injections themselves if they have been trained and have access to expert advice.

For more information about using Ganirelix Gedeon Richter, see the package leaflet or contact your doctor or pharmacist.

How does Ganirelix Gedeon Richter work?

During fertility treatment, ovarian stimulation with FSH or corifollitropin alfa is normally used to make the ovaries produce more than one mature egg. A few days later, a hormone called human chorionic gonadotrophin (hCG) is given to trigger ovulation (the release of eggs) and the mature eggs are harvested for use in techniques such as *in-vitro* fertilisation. In premature ovulation, the ovaries

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release eggs that may be immature and not suitable for these techniques. The active substance in Ganirelix Gedeon Richter, ganirelix, blocks the receptors for a natural hormone called gonadotrophin-releasing hormone (GnRH). GnRH controls the secretion of another hormone called luteinising hormone (LH), which causes ovulation. By blocking the effect of GnRH, Ganirelix Gedeon Richter stops the production of LH, and thereby prevents premature ovulation.

How has Ganirelix Gedeon Richter been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Orgalutran, and do not need to be repeated for Ganirelix Gedeon Richter.

As for every medicine, the company provided studies on the quality of Ganirelix Gedeon Richter. There was no need for 'bioequivalence' studies to investigate whether Ganirelix Gedeon Richter is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Ganirelix Gedeon Richter is very similar to the reference medicine and, when given by injection under the skin, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Ganirelix Gedeon Richter?

Because Ganirelix Gedeon Richter is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Ganirelix Gedeon Richter authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Ganirelix Gedeon Richter has been shown to have comparable quality and to be bioequivalent to Orgalutran. Therefore, the Agency's view was that, as for Orgalutran, the benefits of Ganirelix Gedeon Richter outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Ganirelix Gedeon Richter?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ganirelix Gedeon Richter have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ganirelix Gedeon Richter are continuously monitored. Suspected side effects reported with Ganirelix Gedeon Richter are carefully evaluated and any necessary action taken to protect patients.

Other information about Ganirelix Gedeon Richter

Ganirelix Gedeon Richter received a marketing authorisation valid throughout the EU on 15 July 2022.

Further information on Ganirelix Gedeon Richter can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ganirelix-gedeon-richter. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 07-2022.