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EPAR summary for the public

Orgalutran

ganirelix

This document is a summary of the European Public Assessment Report (EPAR) for Orgalutran. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Orgalutran.

What is Orgalutran?

Orgalutran is a solution for injection in a prefilled syringe. Each syringe contains 0.25 mg of the active substance, ganirelix.

What is Orgalutran used for?

Orgalutran is 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). In premature ovulation, the ovaries release eggs that may be immature and not suitable for use in techniques such as *in-vitro* fertilisation.

The medicine can only be obtained with a prescription.

How is Orgalutran used?

Treatment with Orgalutran should be carried out by a doctor who has experience in this type of fertility treatment.

Orgalutran is given as a single 0.25-mg injection under the skin once a day. 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 Orgalutran should be continued up to the day that there are enough large follicles (small sacs in the ovary that hold the eggs).

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Orgalutran is preferably given into the upper leg. The patient or her partner may give the injections themselves, if they have been trained and have access to expert advice. For further information on how to use Orgalutran, see the package leaflet.

How does Orgalutran work?

The active substance in Orgalutran, 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 (the release of eggs during the menstrual cycle). During fertility treatment, ovarian stimulation is normally used to make the ovaries produce more than one egg. A few days later, a hormone called human chorionic gonadotrophin (hCG) is given to trigger ovulation, and the eggs are then harvested. By blocking the effect of GnRH, Orgalutran stops the production of LH, and therefore prevents premature ovulation.

How has Orgalutran been studied?

The ability of Orgalutran to prevent premature ovulation has been studied in three main studies involving 1,335 women. Orgalutran was compared with buserelin, leuprorelin, and triptorelin (GnRH agonists: another group of medicines used to prevent premature ovulation, which work by stimulating the receptor for GnRH to such an extent that the body stops making LH). The main measures of effectiveness were the number of eggs that could be harvested and the number of women who became pregnant.

What benefit has Orgalutran shown during the studies?

After treatment with Orgalutran, the average number of eggs that could be harvested was between 7.9 and 11.6 per woman. Between 20% and 31% of the women became pregnant. Overall, the values for the GnRH agonists were slightly higher.

What is the risk associated with Orgalutran?

In studies, the most common side effect with Orgalutran (seen in more than 1 patient in 10) was a skin reaction at the injection site, mainly redness with or without swelling. For the full list of all side effects reported with Orgalutran, see the package leaflet.

Orgalutran should not be used in people who may be hypersensitive (allergic) to ganirelix, to any of the other ingredients, to GnRH or to other GnRH analogues (medicines that have a similar structure to GnRH and modify the activity of GnRH in the body). It must not be used by women who are pregnant or breast-feeding, or in women with moderate or severe kidney or liver disease. For the full list of restrictions, see the package leaflet.

Sometimes, the ovaries can over-respond to stimulation. This is called ‘ovarian hyperstimulation syndrome’. Doctors and patients must be aware of this possibility.

Why has Orgalutran been approved?

The CHMP decided that Orgalutran’s benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Orgalutran:

The European Commission granted a marketing authorisation valid throughout the European Union for Orgalutran to N.V. Organon on 17 May 2000. The marketing authorisation is valid for an unlimited period.

The full EPAR for Orgalutran can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Orgalutran, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2011.