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Cetrotide (*cetrorelix*)

An overview of Cetrotide and why it is authorised in the EU

What is Cetrotide and what is it used for?

Cetrotide is a medicine used to prevent premature ovulation (early release of eggs from the ovary). It is given to women having ovarian stimulation (fertility treatment where the ovaries are stimulated to produce more eggs).

Cetrotide contains the active substance cetrorelix.

How is Cetrotide used?

Cetrotide can only be obtained with a prescription and treatment should be carried out by a doctor who has experience in this type of fertility treatment.

Cetrotide is given by injection under the skin of the lower abdomen (belly). The recommended dose is 0.25 mg given every 24 hours, either in the morning or in the evening. Treatment starts usually on day 5 or 6 of ovarian stimulation, continued throughout the ovarian stimulation period, until the evening before or the morning of the day when the induction of ovulation (the release of eggs) is planned.

Because of the risk of severe allergic reactions, the first injection should be supervised by a doctor, and the patient closely watched for 30 minutes. Further injections may be given by the patient herself, as long as she is made aware of the signs of allergic reaction and what to do if they appear. The medicine should be injected slowly at different places on the abdomen every day.

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

How does Cetrotide work?

The active substance in Cetrotide, cetrorelix, blocks the effects of luteinising-hormone-releasing hormone (LHRH) in the body. LHRH controls the production and release of another hormone called luteinising hormone (LH), which causes ovulation. During fertility treatment, ovarian stimulation is

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used to make the ovaries produce more eggs. By blocking the effect of LHRH, Cetrotide stops the production of LH, and therefore prevents premature ovulation, which can result in the release of eggs that are immature and unsuitable for use in techniques such as in vitro fertilisation (IVF).

What benefits of Cetrotide have been shown in studies?

In three main studies, Cetrotide was as effective as the comparator treatments in preventing a surge in the production of LH. The studies involved 814 women and compared Cetrotide with buserelin nasal spray and triptorelin depot injection. These medicines also act on the secretion of LH, but work by overstimulating the production of LHRH, so that the body in response reduces and stops making LH.

Results showed that between 95 and 97% of the patients receiving Cetrotide had no LH surge, compared with 98% for buserelin and 97% for triptorelin. Once the assisted-reproduction procedure was completed, 23% of patients who received Cetrotide became pregnant, compared with 32% in the comparator groups.

What are the risks associated with Cetrotide?

The most common side effects with Cetrotide (which may affect between 1 and 10 patients in 100) are mild to moderate overstimulation of the ovaries (which can occur as a side effect of the ovarian stimulation procedure itself) and reactions at the injection site, such as redness, swelling and itching. Sudden, severe allergic reactions have been reported with Cetrotide and may affect between 1 and 10 patients in 1,000.

Cetrotide must not be used in people who are hypersensitive (allergic) to any hormones that are chemically similar to gonadotropin-releasing hormone, or to extrinsic peptide hormones (hormone medicines similar to Cetrotide). It must not be used in women who are pregnant or breastfeeding, or in patients with severe kidney disease.

For the full list of side effects and restrictions with Cetrotide, see the package leaflet.

Why is Cetrotide authorised in the EU?

Cetrotide is an effective alternative to existing treatments for the prevention of premature ovulation and its side effects are manageable. The European Medicines Agency therefore decided that Cetrotide's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Cetrotide?

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

As for all medicines, data on the use of Cetrotide are continuously monitored. Side effects reported with Cetrotide are carefully evaluated and any necessary action taken to protect patients.

Other information about Cetrotide

Cetrotide received a marketing authorisation valid throughout the EU on 13 April 1999.

Further information on Cetrotide can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cetrotide.

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