EMA/188933/2011
EMEA/H/C/000292

EPAR summary for the public

Luveris

lutropin alfa

This is a summary of the European public assessment report (EPAR) for Luveris. 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 Luveris.

What is Luveris?

Luveris is a medicine that contains the active substance lutropin alfa. It is available as a powder and solvent that are made up into a solution for injection, and as a solution for injection in a pre-filled pen.

What is Luveris used for?

Luveris is a fertility treatment. It is used with follicle stimulating hormone (FSH) to stimulate the development of eggs in the ovaries of adult women who have severe deficiency (very low levels) of luteinising hormone (LH) and FSH.

The medicine can only be obtained with a prescription.

How is Luveris used?

Treatment with Luveris should be carried out by a doctor who has experience in the treatment of fertility problems.

Luveris is given once a day together with FSH. The patient's response to treatment is monitored to check how the egg development in the ovary is progressing. Doses of FSH are adjusted according to the response, and treatment may continue for up to five weeks. Luveris is given by injection under the skin. The patient may carry out the injection herself if she is well-motivated, has been adequately trained and has access to expert advice.

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If the powder and solvent are used, they should be mixed together just before use. The resulting solution can be mixed with FSH in the same syringe.

How does Luveris work?

The active substance in Luveris, lutropin alfa, is a copy of the natural hormone LH. In the body, LH causes the release of eggs (ovulation) during the menstrual cycle. FSH, which is used together with Luveris, also stimulates ovulation.

Lutropin alfa is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce human LH.

How has Luveris been studied?

Luveris, given together with FSH, has been studied in one main study involving 38 women with severe LH and FSH deficiency. Because the number of patients with this condition is low, Luveris was not compared with any other medicines. The main measure of effectiveness was the number of women who produced functional follicles (eggs in the ovaries that are ready for release).

What benefit has Luveris shown during the studies?

In the main study, 67% of the women who received the approved dose of Luveris (75 International Units) together with FSH produced functional follicles (6 out of 9). Higher doses were no more effective than this dose.

What is the risk associated with Luveris?

The most common side effects with Luveris (seen in between 1 and 10 patients in 100) are reactions at the injection site (pain, redness, bruising or swelling), headache,, nausea (feeling sick), vomiting, diarrhoea, abdominal pain and discomfort, pelvic (lower abdominal) pain, mild to moderate ovarian hyperstimulation syndrome, ovarian cyst (development of a fluid-filled cavity in the ovary) and breast pain. Ovarian hyperstimulation syndrome occurs when the ovaries over respond to treatment, especially when medicines to trigger ovulation have been used, and can cause nausea, weight gain and diarrhoea. For the full list of all side effects reported with Luveris, see the package leaflet.

Luveris should not be used in people who may be hypersensitive (allergic) to LH, FSH or any of the other ingredients. It must not be used in women who have tumours of the pituitary gland, hypothalamus (a region of the brain), breast, womb or ovary. It must also not be used when there is enlargement of the ovaries or cysts that are not related to polycystic ovarian disease and are of unknown origin, or unexplained bleeding from the vagina. For the full list of restrictions, see the package leaflet.

Why has Luveris been approved?

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

Other information about Luveris

The European Commission granted a marketing authorisation valid throughout the European Union for Luveris to Merck Serono Europe Limited on 29 November 2000. The marketing authorisation is valid for an unlimited period.

The full EPAR for Luveris 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 Luveris, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2011.