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EPAR summary for the public

Pergoveris

follitropin alfa / lutropin alfa

This is a summary of the European public assessment report (EPAR) for Pergoveris. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Pergoveris.

For practical information about using Pergoveris, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pergoveris and what is it used for?

Pergoveris is a fertility medicine used in women to stimulate the development of follicles, the structures inside the ovaries that contain an egg.

Pergoveris is for adult women who have low levels of two hormones that stimulate the ovaries - follicle-stimulating hormone (FSH) and luteinising hormone (LH).

The medicine contains the active substances follitropin alfa and lutropin alfa.

How is Pergoveris used?

Pergoveris is available as a solution for injection in a pre-filled pen or as a powder and solvent to be made up into a solution for injection. Pergoveris is injected under the skin once a day until the patient has developed a suitable follicle, as assessed using ultrasound scans and by measuring blood oestrogen levels. This may take up to 5 weeks. The recommended starting dose is 150 International Units (IU) of follitropin alfa and 75 IU of lutropin alfa once a day, but this should be tailored to the patient's response. Using less than the recommended starting dose may not be sufficient to stimulate development of a follicle. If necessary, the dose of follitropin alfa can be increased by adding it as a separate medicine, with 7 to 14 days between each dose increase.

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The first injection must be given under direct supervision of a doctor who has experience in the treatment of fertility problems, but the patient can inject herself if she wants to, provided she has been properly trained and has access to expert advice.

The medicine can only be obtained with a prescription. For further information see the package leaflet.

How does Pergoveris work?

The active substances in Pergoveris, follitropin alfa and lutropin alfa, are copies of the natural hormones FSH and LH. In the body, FSH stimulates the production of eggs, and LH stimulates their release. By replacing the missing hormones, Pergoveris allows women with FSH and LH deficiency to develop a follicle, which will release an egg after an injection of the hormone human chorionic gonadotrophin (hCG). This may help these women to become pregnant.

What benefits of Pergoveris have been shown in studies?

Both active substances have already been authorised in the European Union (EU), follitropin alfa as GONAL-f and lutropin alfa as Luveris. Therefore, the company presented information from studies carried out during the development of Luveris to support the use of Pergoveris. In these studies, the combination of follitropin alfa and lutropin alfa at the same doses as in Pergoveris produced active follicles.

The company also carried out bioequivalence studies to establish whether the combined injection produced the same levels of the active substances in the body as the two medicines given separately. These studies confirmed that Pergoveris produced similar blood levels of follitropin alfa and lutropin alfa as when the two medicines are given separately.

What are the risks associated with Pergoveris?

The most common side effects reported with Pergoveris (seen in more than 1 patient in 10) are headache, ovarian cysts and injection site reactions (e.g. pain, itching, redness, bruising, swelling or irritation at the site of injection). Treatment can cause overstimulation of the ovaries (known as ovarian hyperstimulation syndrome, OHSS), which can lead to serious medical problems. Mild or moderate OHSS is common, while severe OHSS is uncommon. Thromboembolism (clots in the blood vessels) may occur very rarely, usually associated with severe OHSS.

Pergoveris must not be used in women who have:

- tumours of the hypothalamus or pituitary gland,
- enlarged ovaries or a cyst on the ovary that is not due to polycystic ovarian disease and is of unknown origin,
- bleeding from the genital region whose cause is unknown,
- cancer of the ovary, womb or breast.

Pergoveris must not be used when a benefit cannot be obtained, such as in women with primary ovarian failure (when the ovaries stop working before the menopause). It must also not be used in women who have malformations of the sexual organs or fibroid tumours of the womb that would stop them from becoming pregnant.

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

Why is Pergoveris approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Pergoveris's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Pergoveris

The European Commission granted a marketing authorisation valid throughout the European Union for Pergoveris on 25 June 2007.

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

This summary was last updated in 03-2017.