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EPAR summary for the public

Ovaleap

follitropin alfa

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

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

What is Ovaleap and what is it used for?

Ovaleap is a medicine that contains the active substance follitropin alfa. It is used to treat the following groups:

- women who do not produce eggs and do not respond to treatment with clomiphene citrate (another medicine that stimulates the ovaries to produce eggs);
- women who are undergoing assisted reproductive techniques (fertility treatment) such as *in-vitro* fertilisation. Ovaleap is given to stimulate the ovaries to produce more than one egg at a time;
- women with severe deficiency (very low levels) of luteinising hormone (LH) and follicle stimulating hormone (FSH). Ovaleap is given together with a medicine containing LH to stimulate the eggs to mature in the ovaries;
- men who have hypogonadotrophic hypogonadism (a rare hormone deficiency disease). Ovaleap is used together with human chorionic gonadotrophin (hCG) to stimulate sperm production.

Ovaleap is a 'biosimilar' medicine. This means that Ovaleap is similar to a biological medicine (the 'reference medicine') that is already authorised in the European Union (EU) and that Ovaleap and the reference medicine contain the same active substance. The reference medicine for Ovaleap is GONAL-f. For more information on biosimilar medicines, see the question-and-answer document here.

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How is Ovaleap used?

Ovaleap is available as a solution for injection. The medicine can only be obtained with a prescription and treatment should be started under the supervision of a doctor who has experience in the treatment of fertility problems.

Ovaleap is given by injection under the skin once a day. The dose of Ovaleap and how often it is given depend on why it is being used and on the patient's response to treatment. After the first injection, the patient or their partner may give the injections themselves, if they are well motivated, have been trained and have access to expert advice.

For further information, see the package leaflet.

How does Ovaleap work?

The active substance in Ovaleap, follitropin alfa, is a copy of the natural hormone FSH. In the body, FSH controls reproductive function: in women, it stimulates the production of eggs; and in men, it stimulates the production of sperm in the testicles.

Previously, the FSH used in medicines was extracted from urine. The follitropin alfa in Ovaleap, as well as in the reference product GONAL-f, is produced by a method known as 'recombinant DNA technology': it is made by cells into which a gene (DNA) has been introduced that makes them able to produce human FSH.

What benefits of Ovaleap have been shown in studies?

Ovaleap has been compared with GONAL-f in one main study involving 299 women undergoing fertility treatment. The main measure of effectiveness was the number of oocytes (immature eggs) collected.

Ovaleap has been shown to be comparable to the reference medicine, GONAL-f. The average number of oocytes collected was 12.2 in the Ovaleap group, compared with 12.0 in the GONAL-f group.

What are the risks associated with Ovaleap?

The most common side effects with Ovaleap (which may affect more than 1 in 10 people) are reactions at the injection site (pain, redness, bruising, swelling or irritation). In women, ovarian cysts (sacs of fluid within the ovaries) and headache are also seen in more than 1 patient in 10. For the full list of all side effects reported with Ovaleap, see the package leaflet.

Ovaleap must not be used in people who are hypersensitive (allergic) to follitropin alfa, FSH, or any of the other ingredients. It must not be used in patients with tumours of the pituitary gland or hypothalamus, or cancer of the breast, womb or ovary. It must not be used when it would not be possible for the patient to have an effective response, such as in patients whose ovaries or testicles do not work or in women who should not get pregnant for medical reasons. In women, Ovaleap must not be used when there is enlargement or a cyst of the ovary caused by something other than polycystic ovarian disease, or when there is unexplained bleeding from the vagina. For the full list of restrictions, see the package leaflet.

In some women, the ovaries can over-respond to stimulation. This is called 'ovarian hyperstimulation syndrome'. Doctors and patients must be aware of this possibility.

Why is Ovaleap approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Ovaleap has been shown to have a comparable quality, safety and efficacy profile to GONAL-f. Therefore, the CHMP's view was that, as for GONAL-f, Ovaleap'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 Ovaleap?

A risk management plan has been developed to ensure that Ovaleap is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ovaleap, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Ovaleap

The European Commission granted a marketing authorisation valid throughout the European Union for Ovaleap on 27 September 2013.

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

This summary was last updated in 09-2013.