EMA/684112/2016
EMEA/H/C/003994

EPAR summary for the public

Rekovelle

follitropin delta

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

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

What is Rekovelle and what is it used for?

Rekovelle is a medicine given to women who are having fertility treatments such as in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI). It is used to stimulate the ovaries to produce several eggs at the time, which can then be collected and fertilised in the laboratory.

Rekovelle contains the active substance follitropin delta.

How is Rekovelle used?

Rekovelle is available as a solution for injection, contained in a cartridge to be used with Rekovelle injection pen. 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.

Rekovelle is given by injection under the skin once a day for several consecutive days during the woman's menstrual cycle starting on day 2 or 3 of the cycle and is continued until sufficient eggs have developed. The starting dose of Rekovelle depends on the woman's bodyweight and on the blood level of the anti-Müllerian hormone (a hormone which indicates how well the ovaries will respond to stimulation). The dose can then be modified in subsequent cycles according to the woman's response. After the first injection, the woman or their partner may be able to give the injections themselves, if they have been trained and have access to expert advice.

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For further information, see the package leaflet.

How does Rekovelle work?

The active substance in Rekovelle, follitropin delta, is a copy of the natural hormone called follicle-stimulating hormone (FSH) which plays a key role in fertility in women by stimulating the production of eggs in the ovaries. Giving extra stimulation with Rekovelle helps increase the number of eggs produced in the ovaries, which means that more eggs can then be collected and fertilised in the laboratory.

What benefits of Rekovelle have been shown in studies?

Rekovelle was compared with GONAL-f (follitropin alfa), another fertility medicine, in one study involving 1,326 women who were undergoing controlled ovarian stimulation for IVF or ICSI. The main measure of effectiveness was the rate of implantation and pregnancy.

The study showed that Rekovelle was as effective as GONAL-f at stimulating the ovaries: around 31% of women (204 out of 665) treated with Rekovelle became pregnant compared with around 32% of women (209 out of 661) treated with GONAL-f. Implantation rates were also similar: around 35% with Rekovelle versus around 36% with GONAL-f.

What are the risks associated with Rekovelle?

The most common side effects with Rekovelle (which may affect between 1 and 10 people in 100) are headache, discomfort and pain in the pelvic area which may arise from the ovaries, nausea (feeling sick) and tiredness and ovarian hyperstimulation syndrome (OHSS). OHSS is when a woman's ovaries over-respond to stimulation, causing symptoms such as vomiting, diarrhoea and pain. In severe cases OHSS may lead to difficulty breathing and problems with blood clotting. The frequency of side effects may decrease with repeated treatment cycles. For the full list of all side effects reported with Rekovelle, see the package leaflet.

Rekovelle must not be used in women with tumours of the pituitary gland or hypothalamus, or cancer of the breast, womb or ovary. Rekovelle must not be used when there is enlargement of an ovary or a cyst that is caused by something other than polycystic ovarian syndrome, or when there is unexplained bleeding from the vagina. For the full list of restrictions, see the package leaflet.

Why is Rekovelle approved?

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

The CHMP considered that Rekovelle was effective in obtaining several eggs at the same time following stimulation in women undergoing fertility treatment. The safety profile of Rekovelle was considered acceptable and similar to that of GONAL-f.

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

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

Other information about Rekovelle

The European Commission granted a marketing authorisation valid throughout the European Union for Rekovelle on 12 December 2016.

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

This summary was last updated in 12-2016.