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Elonva (*corifollitropin alfa*)

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

What is Elonva and what is it used for?

Elonva is a hormonal medicine used in women who are undergoing fertility treatment to stimulate the development of more than one mature egg at a time in the ovaries. It is used together with a gonadotrophin-releasing hormone (GnRH) antagonist (another type of medicine used in fertility treatments).

Elonva combined with another hormonal medicine called human chorionic gonadotropin (hCG) is also used to treat adolescent boys aged 14 years and older who have delayed or absent puberty due to hypogonadotropic hypogonadism. In adolescent males with this condition, production of the hormones that stimulate testicular development is inadequate. Therefore, the testes remain small and produce little or no testosterone. This results in delayed or absent pubertal characteristics, and no sperm production resulting in problems with fertility.

Elonva contains the active substance corifollitropin alfa.

How is Elonva used?

Elonva can only be obtained with a prescription. In women, treatment should be started under the supervision of a doctor experienced in treating fertility problems. In adolescent males, treatment should be started and supervised by a doctor experienced in the treatment of hypogonadotropic hypogonadism.

Elonva is given as an injection under the skin. The patient or their partner, parent or caregiver may carry out the injection if they have been trained. The dose and frequency of administration of Elonva depend on its use and on the patient's age, weight, and response to treatment. For more information about using Elonva, see the package leaflet or contact your doctor or pharmacist.

How does Elonva work?

The active substance in Elonva, corifollitropin alfa, is similar to follicle stimulating hormone (FSH), a natural hormone. FSH regulates the reproductive function in the body: in women it stimulates the growth of eggs in the ovaries and in men it stimulates the maturation of cells that produce

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testosterone and the production of sperm by the testes. In men, it is given in combination with hCG, which stimulates the production of testosterone. In corifollitropin alfa, a peptide (a short chain of amino acids) is attached to FSH to prolong its activity in the body. As a result, a single dose of the medicine is effective for seven days.

What benefits of Elonva have been shown in studies?

Ovarian stimulation

In three main studies involving 3,292 women who needed ovarian stimulation, treatment with a single injection of Elonva was as effective as treatment with follitropin beta (an FSH medicine also used to stimulate the ovaries) given once daily for seven days.

One of the studies involved women weighing 60 kg or less who received a 100 microgram dose of Elonva, and a second study involved women weighing above 60 kg who received a 150 microgram dose. Both these studies involved women aged 18 to 36 years. The main measure of effectiveness for these studies was the average number of eggs collected from each woman after treatment. The study in women over 60 kg had an additional main effectiveness measure which was the number of women with a successful early pregnancy.

In the first study in women weighing 60 kg or less, the number of eggs collected from each woman was 13.3 for those treated with Elonva and 10.6 for those treated with follitropin beta.

In the second study in women weighing more than 60 kg, the average number of eggs collected from each woman was 13.8 in those treated with Elonva compared with 12.6 in those treated with follitropin beta. Around 39% of those who received Elonva became pregnant compared with 38% of those treated with follitropin beta.

The third study involved women aged 35 to 42 years weighing 50 kg or more who were given a 150 microgram dose of Elonva; the main measure of effectiveness in this study was the number of women with a successful early pregnancy, and 24 and 27% of women treated with Elonva and follitropin beta respectively became pregnant.

Hypogonadotropic hypogonadism in adolescent boys

In one main study involving 17 adolescent boys aged 14 years and older with hypogonadotropic hypogonadism, Elonva was effective at stimulating development of the testes (measured by an increase in testicular volume), which is a sign that the number of cells needed for the production of sperm has increased. After a period of 64 weeks of Elonva treatment, 52 of which in combination with hCG, the testicular volume increased by around nine times, from an average of 1.4 ml to an average of 12.9 ml. Further, the addition of hCG resulted in the development of pubertal characteristics, such as development of pubic hair and increase in height.

What are the risks associated with Elonva?

In women, the most common side effects with Elonva (which may affect up to 1 in 10 people) are headache, nausea (feeling sick), tiredness, pelvic pain and discomfort, breast tenderness and ovarian hyperstimulation syndrome (OHSS). OHSS occurs when the ovaries over-respond to treatment, causing abdominal swelling and pain, nausea and diarrhoea.

In adolescent boys, the most common side effects with Elonva (which may affect up to 1 in 10 people) are vomiting, hot flushes and injection site pain.

For the full list of side effects of Elonva, see the package leaflet.

Elonva must not be used in patients with tumours of the ovary, breast, womb, pituitary (a gland located at the base of the brain that produces FSH) or hypothalamus (a region of the brain). It must also not be used in women with abnormal (not menstrual) vaginal bleeding without a known cause, fibroids or malformations of the womb that would prevent pregnancy, primary ovarian failure, enlarged ovaries or ovaries with cysts, or in women with risk factors for OHSS such as polycystic ovarian syndrome. For the full list of restrictions, see the package leaflet.

Why is Elonva authorised in the EU?

The European Medicines Agency decided that Elonva'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 Elonva?

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

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

Other information about Elonva

Elonva received a marketing authorisation valid throughout the European Union on 25 January 2010.

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

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