European Medicines Agency

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Elonva
corifollitropin alfa

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Elonva?
Elonva is a solution for injection that contains the active substance corifollitropin alfa. It is available as a pre-filled syringe (100 and 150 micrograms).

What is Elonva used for?
Elonva is used in women who are undergoing fertility treatment to stimulate the development of more than one mature egg at the time in the ovaries. It is used together with a gonadotrophin-releasing hormone (GnRH) antagonist (a type of medicine also used in fertility treatments).
Elonva can only be obtained with a prescription.

How is Elonva used?
Treatment with Elonva should be started under the supervision of a doctor experienced in treating fertility problems.
Elonva is given once as a single injection under the skin. Women weighing 60 kg or less should receive a 100-microgram dose, while women weighing above 60 kg should receive a 150-microgram dose. The patient or their partner may carry out the injection if they have been properly instructed.
Four or five days after the Elonva injection, depending on how the ovaries have responded, treatment is started with a GnRH antagonist, which prevents the ovaries from releasing their eggs too early. Seven days after the Elonva injection, if further ovarian stimulation is needed, injections of another medicine similar to Elonva, but suitable for daily injection, may be given. Finally, as soon as three eggs are close to maturation, a single injection of a hormone called human chorionic gonadotropin (hCG) is given to release the mature eggs.
The eggs are collected using a surgical procedure. They will then be fertilised in a laboratory and the resulting embryo is implanted in the womb.

How does Elonva work?
The active substance in Elonva, corifollitropin alfa, is a modified follicle stimulating hormone (FSH), a natural hormone in the body. FSH stimulates the production of eggs in the ovaries. In corifollitropin alfa, a peptide (a short chain of amino acids) is attached to the FSH to prolong its activity in the body. As a result a single dose of the medicine can be given to stimulate egg production, thereby replacing daily injections that would be required with other FSH medicines.

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Corifollitropin alfa is produced by a method known as ‘recombinant DNA technology’. This means that it is made by a cell that has received a gene (DNA) and is then able to produce a protein, in this case corifollitropin alfa.

How has Elonva been studied?
The effects of Elonva were first tested in experimental models before being studied in humans. In two main studies involving 1,905 women who needed to have ovarian stimulation, Elonva treatment was compared with treatment with follitropin beta (an FSH medicine also used to stimulate the ovaries). One of the studies involved women weighing 60 kg or less who received a 100-microgram dose of Elonva, while the other study involved women weighing above 60 kg who received a 150-microgram dose. The main measure of effectiveness for both studies was the average number of eggs collected from each woman after treatment. One of the studies had an additional main effectiveness measure which was the number of women who became pregnant. The other study was not large enough to draw strong conclusions about the resulting pregnancies.

What benefit has Elonva shown during the studies?
Treatment with Elonva was as effective as treatment with follitropin beta. In the study in women weighing above 60 kg, the average number of eggs collected from each woman was 13.7 in those treated with Elonva compared with 12.5 in those treated with follitropin beta. Around 39% of those who received Elonva became pregnant compared with 38% of those treated with follitropin beta.
In the 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.

What is the risk associated with Elonva?
The most common side effects with Elonva (seen in between 1 and 10 patients in 100) are headache, nausea (feeling sick), tiredness, pelvic pain and discomfort, breast complaints and ovarian hyperstimulation syndrome (OHSS). OHSS occurs when the ovaries over-respond to treatment, causing abdominal swelling and pain, nausea and diarrhoea. For the full list of all side effects reported with Elonva, see the Package Leaflet.
Elonva should not be used in people who may be hypersensitive (allergic) to corifollitropin alfa or any of the other ingredients. It 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 primary ovarian failure, enlarged ovaries or ovaries with cysts or in women with a history of OHSS. For the full list of restrictions, see the Package Leaflet.

Why has Elonva been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Elonva’s benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Elonva:
The European Commission granted a marketing authorisation valid throughout the European Union for Elonva to N.V. Organon on 25 January 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Elonva can be found here.

This summary was last updated in 12-2009.