

Elonva®
100 micrograms/0,5 ml
Elonva®
150 micrograms/0,5 ml
solution for injection
corifollitropin alfa

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Elonva is and what it is used for
2. Before you use Elonva
3. How to use Elonva
4. Possible side effects
5. How to store Elonva
6. Further information

1. WHAT ELONVA IS AND WHAT IT IS USED FOR

Elonva is a medicine belonging to the group of gonadotropic hormones. Gonadotropic hormones play an important role in human fertility and reproduction. One of these gonadotropic hormones is follicle-stimulating hormone (FSH), which is needed in women for the growth and development of eggs in the ovaries. Elonva is used to help achieve pregnancy in women having infertility treatment, such as in vitro fertilisation (IVF). IVF involves collecting the eggs from the ovary, fertilising them in the laboratory, and transferring the embryos back into the womb a few days later. Elonva causes the growth of several eggs at the same time by a controlled stimulation of the ovaries.

2. BEFORE YOU USE ELONVA

Do not use Elonva if you

- are allergic (hypersensitive) to corifollitropin alfa or any of the other ingredients of Elonva (for a list of all ingredients, see Section 6)
- have cancer of the ovary, breast, womb, or brain (pituitary gland or hypothalamus)
- have recently had unexpected vaginal bleeding, other than menstrual, without a diagnosed cause
- have ovaries that do not work because of a condition called primary ovarian failure
- have ovarian cysts or enlarged ovaries
- have had ovarian hyperstimulation syndrome (OHSS), see below for further explanation
- have previously had a treatment cycle of controlled stimulation of the ovaries that resulted in the growth of more than 30 eggs with a size of 11 mm or larger
- have a basal antral follicle count (the number of small follicles present in your ovaries at

the beginning of a menstrual cycle) higher than 20

- have malformations of the sexual organs which make a normal pregnancy impossible
- have fibroids in the womb which make a normal pregnancy impossible

Take special care with Elonva

Ovarian hyperstimulation syndrome (OHSS)
Treatment with gonadotropic hormones like Elonva may cause **ovarian hyperstimulation syndrome (OHSS)**. This is a condition where the eggs growing in the ovaries become larger than normal. This may be noticed as severe abdominal swelling and pain in the stomach (abdomen), feeling sick or diarrhoea. Therefore, close supervision by your doctor is very important. To check the effects of treatment, ultrasound scans of the ovaries are usually made, and blood or urine samples may be regularly taken (see also Section 4).

You may use Elonva only once during the same treatment cycle, as otherwise the chance of having OHSS may increase.

Before starting to use this medicine, it is important to inform your doctor if you:

- ever had ovarian hyperstimulation syndrome (OHSS)
- have polycystic ovarian syndrome (PCOS)
- have kidney disease.

Thrombosis
Treatment with gonadotropic hormones like Elonva may (just as pregnancy) increase the chance of having a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel, which occurs most often in the legs or the lungs. Please discuss this with your doctor, before starting treatment, especially if:

- you know you already have an increased chance of having a thrombosis
- you, or anyone in your immediate family, have ever had a thrombosis
- you are severely overweight.

Multiple births or birth defects

There is an increased chance of having twins or even more than two babies if more than one embryo is transferred back into the womb. Multiple pregnancies carry an increased health risk for both the mother and her babies. Multiple pregnancies and specific characteristics of couples with fertility problems (e.g. age) may also be associated with an increased chance of birth defects.

Pregnancy complications

If treatment with Elonva results in pregnancy, there is a higher chance of pregnancy outside the womb (an ectopic pregnancy) in women with damaged fallopian tubes (the tubes which carry the egg from the ovary to the womb). Therefore, your doctor should perform an early ultrasound examination to exclude the possibility of pregnancy outside the womb.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You should not use Elonva if you are already pregnant, or suspect that you might be pregnant, or if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Elonva may cause dizziness. If you feel dizzy, you should not drive or use machines.

Important information about some of the ingredients of Elonva
This medicinal product contains less than 1 mmol sodium (23 mg) per injection, i.e. essentially ‘sodium-free’.

3. HOW TO USE ELONVA

Always use Elonva exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Elonva is used in women having infertility treatment like in vitro fertilisation (IVF). During this treatment Elonva is used in combination with a medicine to prevent too early ovulation (so called GnRH-antagonist). Treatment with the GnRH-antagonist usually starts 4 to 5 days after the injection of Elonva.

The use of Elonva in combination with a GnRH agonist (another medicine to prevent too early ovulation) is not recommended. It may lead to a higher stimulation of your ovaries.

Dose

- If your body weight is 60 kilograms or lower, a single dose of 100 micrograms of Elonva should be injected on one of the first days of your period (menstruation), as instructed by your doctor.
- If your body weight is more than 60 kilograms, a single dose of 150 micrograms of Elonva should be injected on one of the first days of your period (menstruation), as instructed by your doctor.

During the first seven days after the injection with Elonva, you should not use (recombinant) Follicle Stimulating Hormone ((rec)FSH). Seven days after the injection of Elonva, your doctor may decide to continue treatment with another gonadotropic hormone, like (rec)FSH. This

may be continued for a few days until enough eggs of adequate size are present. This can be checked by ultrasound examination. Treatment with (rec)FSH is then stopped and the eggs are matured by giving hCG (human Chorionic Gonadotropin). The eggs are collected from the ovary 34-36 hours later.

How Elonva is given

Treatment with Elonva should be supervised by a physician experienced in the treatment of fertility problems. Elonva must be injected under the skin (subcutaneously) into a skin fold, just below the navel. The injection may be given by a healthcare professional (for example a nurse), your partner or yourself, if carefully instructed by your doctor. Always use Elonva exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. A step-by-step “instructions for use” is given at the end of this leaflet. When the instructions are followed carefully, Elonva will be given properly and with minimal discomfort. Do not inject Elonva into a muscle.

If you use more Elonva or (rec)FSH than you should

If you use one pre-filled syringe of Elonva, it is not possible to inject more than you should. Using too much Elonva or (rec)FSH may occur if Elonva is used more than once during a treatment cycle, or if (rec)FSH is used during the first seven days after the injection with Elonva (see also “How to use Elonva”). This may increase the risk of ovarian hyperstimulation syndrome (OHSS). If you think you have used more Elonva or (rec)FSH than you should, contact your doctor immediately.

If you forget to use Elonva

If you forgot to inject Elonva on the day you

should have, contact your doctor immediately.

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Elonva can cause side effects, although not everybody gets them. The chance of having a side effect is described by the following categories:

Common (affects 1 to 10 users in 100)

- Ovarian hyperstimulation syndrome (OHSS)
- Headache
- Feeling sick
- Tiredness (fatigue)
- Pelvic pain and discomfort
- Breast complaints (including tenderness)

Uncommon (affects 1 to 10 users in 1,000)

- Ovarian torsion
- Dizziness
- Vomiting
- Pain in the stomach (abdomen)
- Intestinal complaints (such as diarrhoea, constipation and abdominal distension)

A possible complication of treatment with gonadotropic hormones like Elonva is unwanted overstimulation of the ovaries. The chance of having this complication can be reduced by carefully monitoring the number of maturing eggs as well as your hormones during treatment. Your doctor will take care of that. The first symptoms of ovarian overstimulation may be noticed as pain in the stomach (abdomen), feeling sick or diarrhoea. Ovarian overstimulation may develop into a medical condition called ovarian hyperstimulation syndrome (OHSS), which can be a serious medical problem. In more severe

cases this may lead to enlargement of the ovaries, collection of fluid in the abdomen and/or chest (which may cause weight gain) or clots in the blood vessels. Contact your doctor without delay if you have pain in the stomach (abdomen) or any of the other symptoms of ovarian hyperstimulation, even if they occur some days after the injection has been given.

Pregnancy outside the womb, miscarriage and multiple pregnancies have also been reported. These side effects are not considered to be related to the use of Elonva, but to the Assisted Reproductive Technology (ART) program or subsequent pregnancy.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE ELONVA

Keep out of the reach and sight of children.

Do not use Elonva after the expiry date which is stated on the label and outer carton after “EXP” (expiry date). The expiry date refers to the last day of the indicated month.

Storage by the pharmacist

Store in a refrigerator (2°C-8°C). Do not freeze.

Storage by the patient

There are two options:

1. Store in a refrigerator (2°C-8°C). Do not freeze.
2. Store at or below 25°C for a period of not more than one month. Make a note of when you start storing the product out of the refrigerator, and use it within one month of that date.

Keep the syringe in the outer carton in order to protect from light.

Do not use Elonva

- if it has been stored out of the refrigerator for more than one month.
- if it has been stored out of the refrigerator at a temperature of more than 25°C.
- if you notice that the solution is not clear.
- if you notice that the syringe or the needle is damaged.

An empty or unused syringe should not be disposed of via household waste. Ask your pharmacist or doctor how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Elonva contains

- The active substance is corifollitropin alfa. Each pre-filled syringe contains 100 micrograms in 0.5 millilitre (ml) solution for injection.
- The active substance is corifollitropin alfa. Each pre-filled syringe contains 150 micrograms in 0.5 millilitre (ml) solution for injection.
- The other ingredients are: sodium citrate, sucrose, polysorbate 20, methionine and water for injections. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.
- Elonva is available in two strengths: 100 micrograms and 150 micrograms solution for injection.

What Elonva looks like and contents of the pack

Elonva is a solution for injection (injection) in a pre-filled syringe with an automatic safety system, which prevents needle stick injuries

after use. The syringe is packed together with a sterile injection needle.

One pre-filled syringe is available in a single pack.

Elonva is a clear and colourless solution for injection.

Marketing Authorisation Holder
N.V. Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands.

Manufactured by:

- Vetter Pharma-Fertigung GmbH & Co. KG, Schützenstrasse 87, 99 and 101, 88212 Ravensburg, Germany

Release site:

- Organon (Ireland) Ltd., Drynam Road, Swords, Co. Dublin, Ireland.

This leaflet was last approved in January 2010.

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

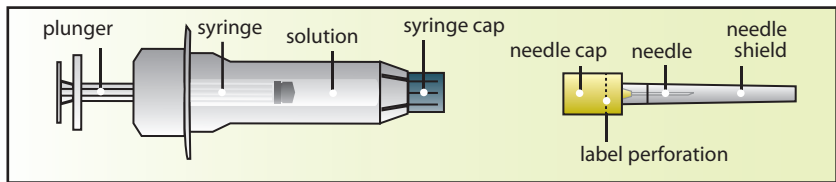
Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

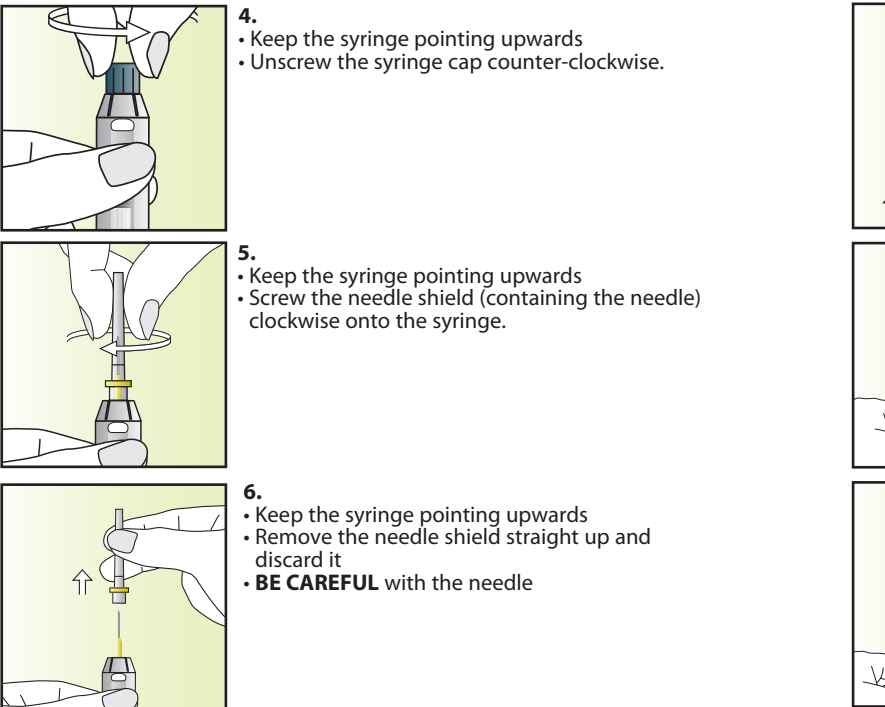
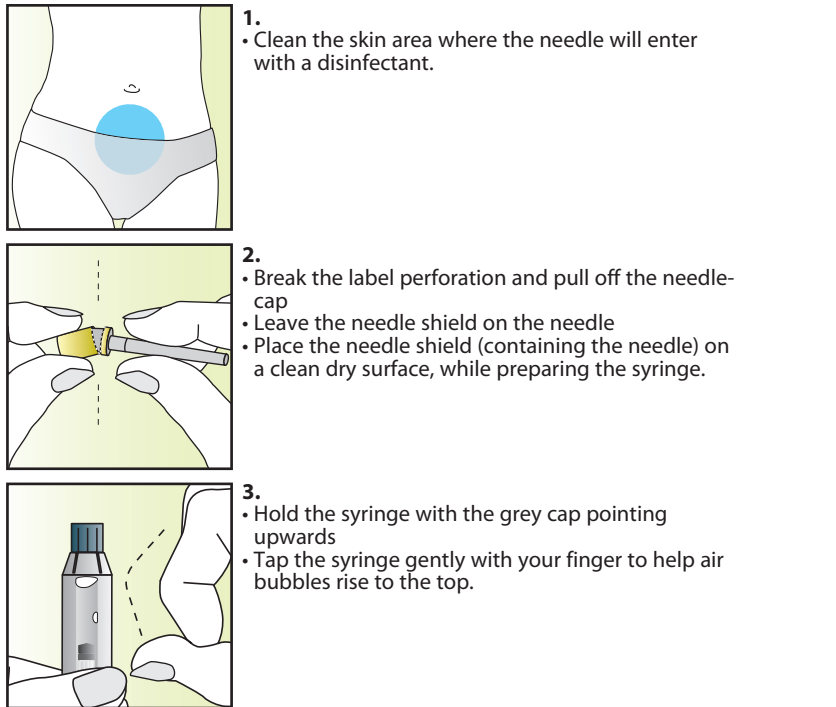


Instructions for use

Components of the Elonva syringe with needle



Preparing the injection



Injecting

