PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine can be sold under doctor's prescription only

ELONVA® 100 mcg/0.5 ml
Solution for injection

ELONVA® 150 mcg/0.5 ml
Solution for injection

Active ingredient and its concentration:
ELONVA 100 mcg/0.5 ml contains:
Corifollitropin alfa 100 mcg/0.5 ml, solution for injection
ELONVA 150 mcg/0.5 ml contains:
Corifollitropin alfa 150 mcg/0.5 ml, solution for injection
Inactive ingredients - see section 6.1 "What **ELONVA** contains"

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- This leaflet contains concise information about **ELONVA**. If you have any further questions, 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, consult your doctor or pharmacist.

In this leaflet:

1. WHAT IS ELONVA AND WHAT IS IT USED FOR?

1.1 What is ELONVA?

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.

1.2 What is ELONVA used for?

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, fertilizing 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

2.1 When not to 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 inactive 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

2.2 Special warnings concerning use of ELONVA

2.2.1 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.

2.2.2 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.

2.2.3 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.

2.2.4 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.

2.3 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 and food supplements.

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

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

2.6 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** as instructed by the doctor. Check with your doctor or pharmacist if you are unsure.
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.

3.1 Recommended dosage

- 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.

3.2 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.
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.

3.3 If you accidentally take a dosage higher 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.

3.4 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 or pharmacist.

4. SIDE EFFECTS

Like all medicines, **ELONVA** can cause side effects, although not everybody gets them. Do not be alarmed by reading the list of side effects, you may not suffer from any of 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
- Nausea
- 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, consult your doctor.

5. HOW TO STORE ELONVA?

- **Avoid Poisoning!** This medicine, and all other medicines must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
- 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.
- Keep **ELONVA** out of the reach and sight of children.
- Storage conditions:
  Storage by the pharmacist:
  Store in a refrigerator (2ºC-8ºC: this temperature range exists in most household refrigerators). Do not freeze.
  Storage by the patient:
  There are two options:
  1. Store in a refrigerator (2ºC-8ºC: this temperature range exists in most household refrigerators). Do not freeze.
  2. Store at or below 25ºC 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 25ºC.
- 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
6.1 What ELONVA contains
- In addition to the active ingredient the solution also contains inactive ingredients: Sodium citrate dihydrate, sucrose, polysorbate 20, L-methionine and water for injections. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

6.2 What ELONVA looks like and content of the pack
ELONVA is a solution for 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.
ELONVA is available in two strengths: 100 microgram and 150 microgram solution for injection.

Manufacturer:
N.V. Organon, Oss, The Netherlands.

Marketing authorization holder:
Merck Sharp & Dohme (Israel - 1996) Company Ltd., P.O.B. 7121, Petah-Tikva 49170.

Drug registration no. listed in the official registry of the Ministry of Health:
ELONVA 100 mcg/0.5 ml: 147.30.33282
ELONVA 150 mcg/0.5 ml: 147.31.33283

This leaflet was checked and approved by the Ministry of Health in January 2012.

Instructions for use

Components of the ELONVA syringe with needle (Fig. 1)

Preparing the injection

1. (Fig. 2)
- Clean the skin area where the needle will enter with a disinfectant.

2. (Fig. 3)

- Break the label perforation and pull off the needle-cap
- Leave the needle shield on the needle
- Place the needle shield (containing the needle) on a clean dry surface, while preparing the syringe.

3. (Fig. 4)
- Hold the syringe with the grey cap pointing upwards
- Tap the syringe gently with your finger to help air bubbles rise to the top.

4. (Fig. 5)
- Keep the syringe pointing upwards
- Unscrew the syringe cap counter-clockwise.

5. (Fig. 6)
- Keep the syringe pointing upwards
- Screw the needle shield (containing the needle) clockwise onto the syringe.

6. (Fig. 7)
- Keep the syringe pointing upwards
- Remove the needle shield straight up and discard it
- Be careful with the needle

Injecting

7. (Fig. 8)
- Now take the syringe between index and middle finger in the upward position
- Place your thumb on the plunger
- Carefully push the plunger upwards until a tiny droplet appears at the tip of the needle.

8. (Fig. 9)
- Pinch a fold of the skin between thumb and index finger
- Insert the entire needle at an angle of 90 degrees into the fold of the skin
- CAREFULLY press the plunger until it can not go further and hold the plunger down
- COUNT TO FIVE to ensure that all of the solution is injected.

9. (Fig. 10)
- Release your thumb from the plunger
- The needle will withdraw automatically into the syringe where it will be locked permanently.

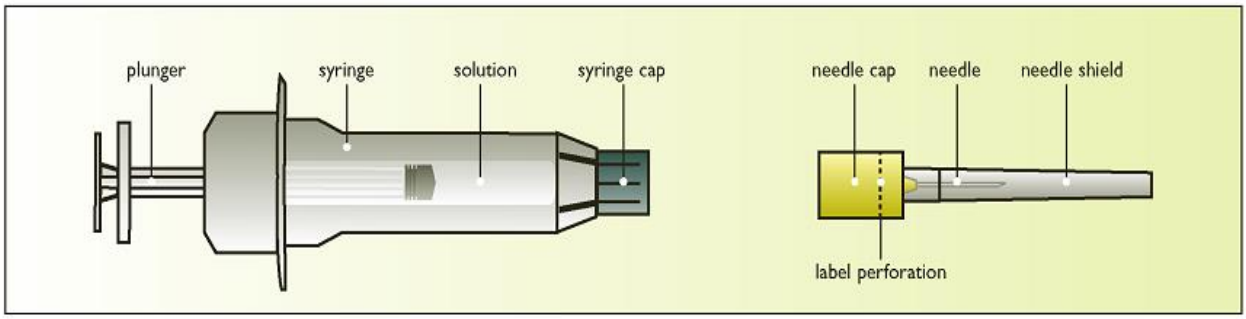

Fig. 1

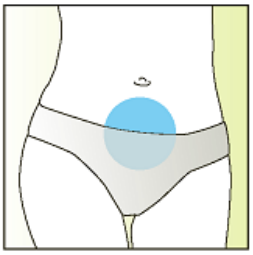

Fig. 2

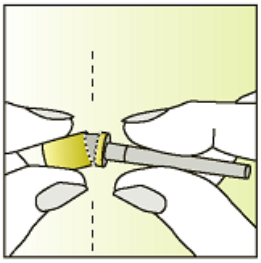

Fig. 3

Fig. 4

Fig. 5

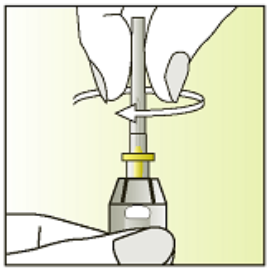

Fig. 6

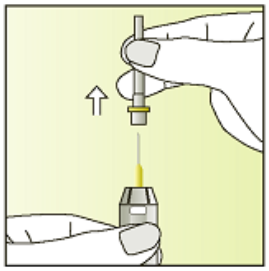

Fig. 7

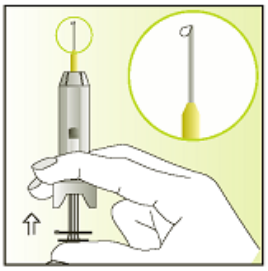

Fig. 8

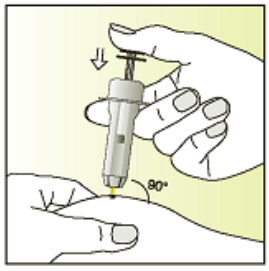

Fig. 9

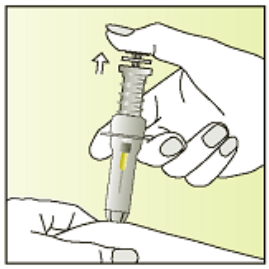

Fig. 10