

ELONVA[®] SOLUTION FOR INJECTION

corifollitropin alfa (100 mcg/0.5ml, 150 mcg/0.5ml)

What is in this leaflet

1. What *ELONVA* is used for
2. How *ELONVA* works
3. Before you use *ELONVA*
4. How to use *ELONVA*
5. While you are using it
6. Side effects
7. Storage and Disposal of *ELONVA*
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What *ELONVA* is used for

ELONVA is used to help achieve pregnancy in women undergoing infertility treatment.

How *ELONVA* works

ELONVA contains corifollitropin alfa, 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 follicles.

ELONVA is especially designed to work much longer than FSH. One single injection of *ELONVA* can replace a whole week of daily FSH injections in women having infertility treatment, such as *in vitro* fertilization (IVF). IVF involves collecting the follicles from the ovary, fertilizing them in the laboratory, and transferring the embryos into the uterus a few days later.

ELONVA causes the growth and development of several follicles (small round sacs in your ovaries that contain the eggs) at the same time by a controlled stimulation of the ovaries.

Before you use *ELONVA*

- When you must not use it

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 “**Product Description**”)

- are pregnant or think you may be pregnant
- have **cancer** of the ovary, breast, uterus, 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 polycystic ovarian syndrome (PCOS)
- 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 follicles 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 **fibroid tumors in the uterus** which make a normal pregnancy impossible.

- Before you start to use it

Chance of having ovarian hyperstimulation syndrome (OHSS)

Treatment with gonadotropic hormones like *ELONVA* may cause **ovarian hyperstimulation syndrome (OHSS)**. This is a serious medical condition where the ovaries are overly stimulated and the growing follicles become larger than normal. In rare cases, severe OHSS may be life-threatening. Therefore, close supervision by your doctor is very important. To check the effects of treatment, your doctor will do ultrasound scans of your ovaries to carefully monitor the number of

maturing follicles. Your doctor may also check blood hormone levels (see also “**Side effects**”).

OHSS causes fluid to build up suddenly in your stomach and chest areas and can cause blood clots to form. **Call your doctor right away without delay** if you have any of the following symptoms, even if they occur some days after the injection has been given:

- severe abdominal swelling and pain in the stomach area (abdomen)
- feeling sick (nausea)
- vomiting
- sudden weight gain due to fluid buildup
- diarrhoea.
- decrease urine output
- trouble breathing

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

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

- have ever had ovarian hyperstimulation syndrome (OHSS)

Ovarian Torsion

Ovarian torsion is the twisting of an ovary. Twisting of the ovary could cause the blood flow to the ovary to be cut off.

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

- are pregnant or think that you may be pregnant.
- have ever had stomach (abdominal) surgery.
- have ever had a twisting of an ovary.
- have past or current cysts in your ovary or ovaries

Chance of having a blood clot (thrombosis)

Treatment with gonadotropic hormones like *ELONVA* (just as pregnancy) may increase the risk of

ELONVA[®] SOLUTION FOR INJECTION

corifollitropin alfa (100 mcg/0.5ml, 150 mcg/0.5ml)

having a blood clot (**thrombosis**). Thrombosis is the formation of a blood clot in a blood vessel.

Blood clots can cause serious medical conditions, such as:

- blockage in your lungs (pulmonary embolus)
- stroke
- heart attack
- blood vessel problems (thrombophlebitis)
- a lack of blood flow (deep venous thrombosis) that may result in a loss of your arm or leg

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.

Chance of having multiple births or birth defects

There is an increased chance of having twins or even more than two babies, even when only one embryo is transferred into the uterus. 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. a woman's age, certain sperm problems, genetic background of both parents) may also be associated with an increased chance of birth defects.

Chance of having pregnancy complications

If treatment with *ELONVA* results in pregnancy, there is a higher chance of pregnancy outside the uterus (an ectopic pregnancy). Therefore, your doctor should perform an early ultrasound examination to exclude the possibility of pregnancy outside the uterus.

The chance of having multiple births, and chance of having pregnancy complications are not considered to be related to the use of *ELONVA*, but to Assisted Reproductive Technology (ART) or subsequent pregnancy.

Ovarian and Other Reproductive System Tumors

There have been reports of ovarian and other reproductive system tumors in women who have had infertility treatment. It is not known if treatment with fertility medicines increases the risk of these tumors in infertile women.

Other medical conditions

In addition, before starting to use this medicine, tell your doctor if you:

- have kidney disease.
- have uncontrolled pituitary gland or hypothalamic problems.
- have an underactive thyroid gland (hypothyroidism).
- have adrenal glands that are not working properly (adrenocortical insufficiency).
- have high prolactin levels in the blood (hyperprolactinemia).
- have any other medical conditions (for example, diabetes, heart disease, or any other long-term disease).
- have been told by a doctor that pregnancy would be dangerous for you.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. You should not use *ELONVA* if you are already pregnant, or suspect that you might be pregnant, or if you are breast-feeding.

-Taking 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.

How to use *ELONVA*

- How much to use, When to use it and How long to use it

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* fertilization (IVF). During this treatment, *ELONVA* is used in combination with a medicine (so called GnRH-antagonist) to prevent your ovary from releasing an egg too early. Treatment with the GnRH-antagonist usually starts 5 to 6 days after the injection of *ELONVA*.

The use of *ELONVA* in combination with a GnRH agonist (another medicine to prevent your ovary from releasing an egg too early) is not recommended.

Dose

In the treatment of women of reproductive age, the dose of *Elonva* is based on weight and age.

		Body Weight		
		Less than 50 kg	50-60 kg	More than 60 kg
Age	36 years or younger	100 micrograms	100 micrograms	150 micrograms
	Older than 36 years	Not studied	150 micrograms	150 micrograms

You should not use (recombinant) Follicle Stimulating Hormone ((rec)FSH) for the first seven days after the injection with *ELONVA*. Seven days after the injection of *ELONVA*, your doctor may decide to continue your stimulation cycle with another gonadotropic hormone, like (rec)FSH. This may be continued for a few days until enough follicles of adequate size are present. This can be checked by ultrasound

ELONVA[®] SOLUTION FOR INJECTION

corifollitropin alfa (100 mcg/0.5ml, 150 mcg/0.5ml)

examination. Treatment with (rec)FSH is then stopped and the follicles are matured by giving hCG (human Chorionic Gonadotropin). The follicles 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 (that you pinch between your thumb and index finger), preferably 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.

Do not inject ELONVA into a muscle.

- If you forget to use it

If you forgot to inject ELONVA on the day you should have, **contact your doctor immediately**. Do not inject ELONVA without talking with your doctor.

- If you use too much (overdose)

If you think you have used more ELONVA or additional medicines (for example, follicle-stimulating hormone) that make your ovaries continue to grow mature eggs than you should, contact your doctor immediately. It may increase the risk of OHSS.

While you are using ELONVA

- Things you must do

See your doctor regularly so you can be monitored closely throughout your treatment.

- If you have any further questions, please ask your doctor or pharmacist.

- Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Driving and using machines

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

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)
- Pelvic pain
- Feeling sick (nausea)
- Headache
- Pelvic discomfort
- Breast tenderness
- Tiredness (fatigue)

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

- Twisting of an ovary (ovarian torsion)
- Liver enzyme increases
- Miscarriage
- Procedural pain
- Releasing an egg too early (premature ovulation)
- Abdominal distension
- Vomiting
- Diarrhoea
- Constipation
- Back pain
- Breast pain
- Bruising or pain at the injection site
- Irritability
- Mood swings
- Dizziness
- Hot flush

In general use there have been reports of allergic reactions

(hypersensitivity reactions, including rash).

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**.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of ELONVA

- Storage

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.

There are two options:

- 1 Store in a refrigerator (2°C-8°C) until the expiry date. 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.

- Disposal

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

ELONVA[®] SOLUTION FOR INJECTION

corifollitropin alfa (100 mcg/0.5ml, 150 mcg/0.5ml)

waste. Ask your pharmacist or doctor how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

ELONVA is a clear and colourless aqueous solution for injection.

ELONVA is a solution for injection in a pre-filled syringe for single use.

The syringe has 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 available in two strengths: 100 micrograms and 150 micrograms solution for injection.

- Ingredients

- Active ingredient

The active substance is corifollitropin alfa.

Elonva 100 micrograms solution for injection: Each pre-filled syringe contains 100 micrograms in 0.5 milliliter (mL) solution for injection.

Elonva 150 micrograms solution for injection: Each pre-filled syringe contains 150 micrograms in 0.5 milliliter (mL) solution for injection.

- Inactive ingredients

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.

- MAL number

ELONVA 100 micrograms solution for injection:
MAL20102082ACRZ

ELONVA 150 micrograms solution for injection:
MAL20102083ACRZ

Manufacturer

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

Product Registration Holder

Organon Malaysia Sdn. Bhd.
3A-08-02, Level 8,
Corporate Tower 3A,
Pavilion Damansara Heights,
No. 3, Jalan Damanlela
50490 Kuala Lumpur,
Malaysia.

Date of revision

09/01/2026 (version 062017)

Serial number

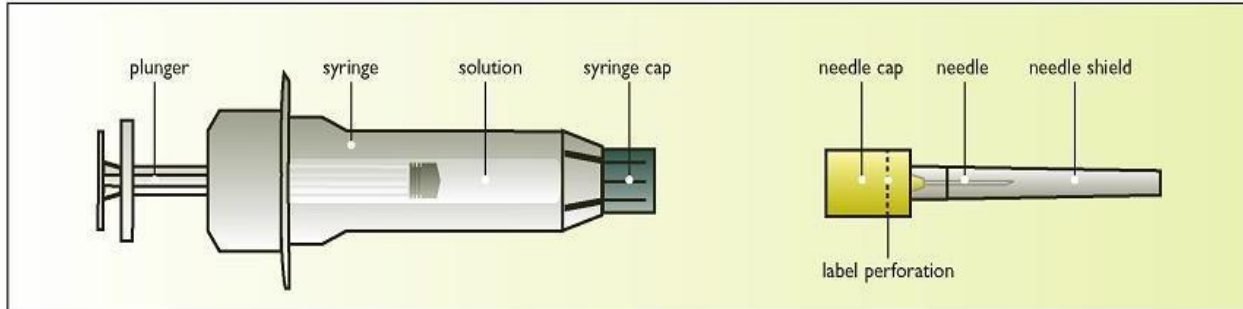
NPRA(R3/01)08102021/0146

ELONVA[®] SOLUTION FOR INJECTION

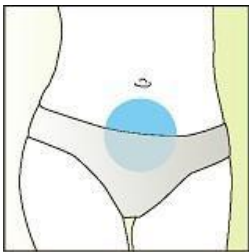
corifollitropin alfa (100 mcg/0.5ml, 150 mcg/0.5ml)

Instructions for use

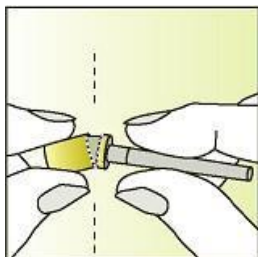
Components of the ELONVA syringe with needle



Preparing the injection



- Wash your hands with soap and water and dry them before you use *ELONVA*.
 - Swab the injection site (the area just below your belly button) with a disinfectant (for example, alcohol) to remove any surface bacteria.
 - Clean about two inches (5 cm) around the point where the needle will go in and let the disinfectant dry for at least one minute before proceeding.



- While waiting for the disinfectant to dry, 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.



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



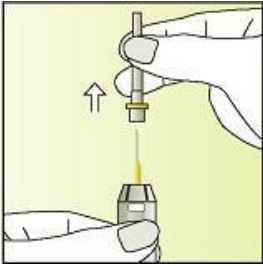
- Keep the syringe pointing upwards.
 - Unscrew the syringe cap counter-clockwise.



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

ELONVA[®] SOLUTION FOR INJECTION

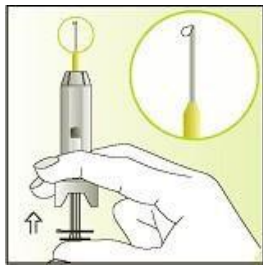
corifollitropin alfa (100 mcg/0.5ml, 150 mcg/0.5ml)



- 6.

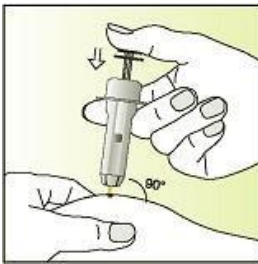
 - Keep the syringe pointing upwards.
 - Remove the needle shield straight up and discard it.
 - Be careful with the needle.

Injecting



- 7.

 - 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.

 - 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.

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