

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Elonva®, 100 micrograms/0.5 mL solution for injection**

**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 solution for injection in a syringe for single use. The syringe has an automatic safety system, which prevents needle stick injuries after use. It contains the active ingredient corifollitropin alfa and belongs to the group of medicines called 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 (small round sacs in your ovaries that contain the eggs).

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 eggs from the ovary, fertilizing them in the laboratory, and transferring the embryos into the uterus a few days later.

Elonva is used to help achieve pregnancy in women undergoing infertility treatment. It causes the growth and development of several follicles 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)
- 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 **malformations of the sexual organs** which make a normal pregnancy impossible
- have **fibroid tumors in the uterus** which make a normal pregnancy impossible
- have risk factors of OHSS (OHSS is a serious medical problem that can happen when the ovaries are overly stimulated. See below for further explanation.):
  - have polycystic ovarian syndrome (PCOS)
  - have had ovarian hyperstimulation syndrome (OHSS)
  - 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

**Take special care with Elonva**

**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. Your doctor may also check blood hormone levels. (See also Section 4.)

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 if you have :

- severe abdominal swelling and pain in the stomach area (abdomen)
- feeling sick (nausea)
- vomiting
- sudden weight gain due to fluid buildup
- diarrhea
- Decreased urine output
- Trouble breathing

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:

- 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 :

- have ever had ovarian hyperstimulation syndrome (OHSS)
- 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 may (just as pregnancy) increase the risk of 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.

### **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

### **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**

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.

### **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 fertilization (IVF). During this treatment Elonva is used in combination with a medicine to (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.

- A single 100-microgram dose is recommended in women who weigh less than or equal to 60 kilograms and who are 36 years of age or younger.
- A single 150-microgram dose is recommended in women:
  - who weigh more than 60 kilograms, regardless of age.
  - who weigh 50 kilograms or more and who are older than 36 years of age.

Women older than 36 years of age who weighed less than 50 kilograms were not studied.

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

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 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 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 (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. 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.

Do not inject Elonva into a muscle.

Elonva is supplied in pre-filled syringes that have an automatic safety system to prevent needle stick injuries after use.

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

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**.

### **If you forget to use Elonva**

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.

#### 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)
- 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
- Pain after oocyte retrieval
- 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

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 follicles. 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. 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 sudden weight gain due to fluid build up) 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.

In general use there have been reports of allergic reactions (hypersensitivity reactions, both local and generalized, including rash).

Pregnancy outside the uterus, (an ectopic pregnancy) 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) 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) until dispensed or until the expiry date, whichever occurs first. Do not freeze.

### **Storage by the patient**

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.

**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**

- Elonva 100 mcg Solution for Injection : The active substance is corifollitropin alfa. Each pre-filled syringe contains 100 micrograms in 0.5 millilitre (mL) solution for injection.
- Elonva 150 mcg 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 per 0.5 millilitre solution for injection and 150 micrograms per 0.5 millilitre solution for injection.

**What Elonva looks like and contents 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 colorless aqueous solution for injection.

**Product Registrant:**

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Singapore 189720

Zuellig Pharma (B) Sdn Bhd  
Unit 5, 1st floor,  
Spg 607, Jalan Gadong,  
Kg Beribi, BSB, BE1118  
Brunei Darussalam

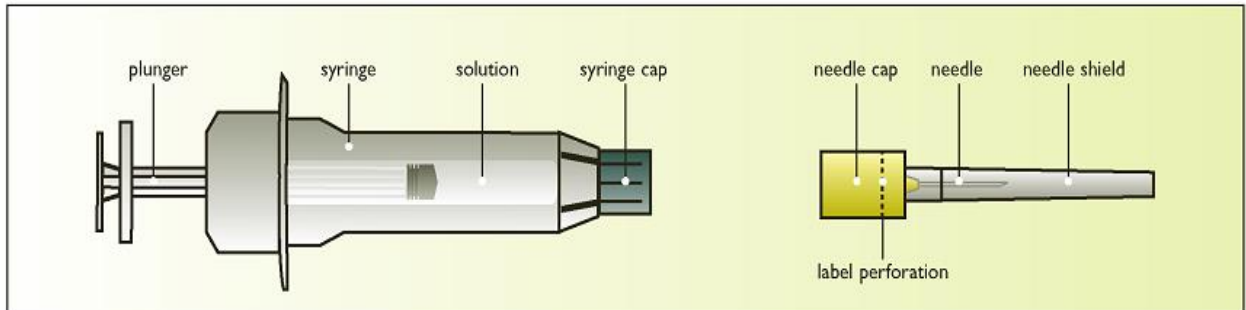
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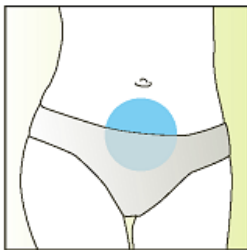


## Instructions for use

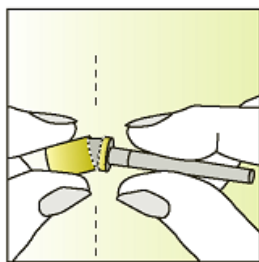
### Components of the Elonva syringe with needle



### Preparing the injection



1.
  - 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 5 cm around the point where the needle will go in and let the disinfectant dry for at least one minute before proceeding.

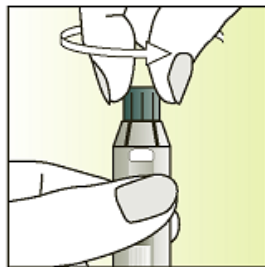


2.
  - While waiting for the disinfectant to dry, break the label perforation and pull off the needle-cap.
  - Leave the needle shield on the needle.
  - Place the needle shield (containing the needle) on a clean dry surface, while preparing the syringe.



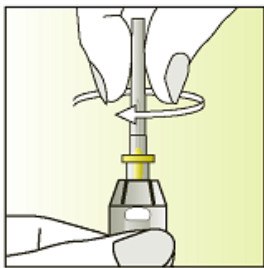
3.

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



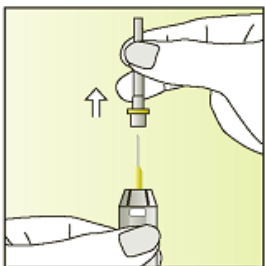
4.

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



5.

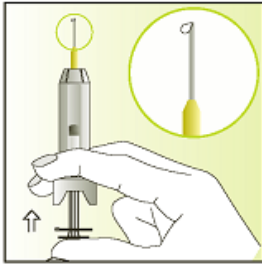
- Keep the syringe pointing upwards.
- Screw the needle shield (containing the needle) clockwise onto the syringe.



6.

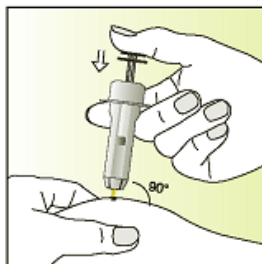
- Keep the syringe pointing upwards.
- Remove the needle shield straight up and discard it.
- **BE CAREFUL** with the needle.

## Injecting



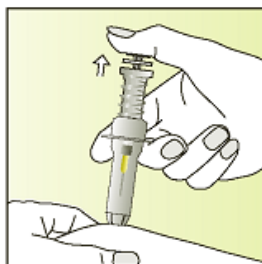
7.

- 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.