

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ELONVA?

ELONVA contains the active ingredient corifollitropin alfa (rch). ELONVA is used to help achieve pregnancy in women having infertility treatment, such as IVF.

For more information, see Section [1. Why am I using ELONVA?](#) in the full CMI.

### 2. What should I know before I use ELONVA?

Do not use if you have ever had an allergic reaction to ELONVA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ELONVA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ELONVA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ELONVA?

- Your doctor will decide the correct dose of ELONVA for you.
- If you are self-administering ELONVA injection, consult the instructions at the end of this leaflet.

More instructions can be found in Section [4. How do I use ELONVA?](#) in the full CMI.

### 5. What should I know while using ELONVA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ELONVA.</li><li>• See your doctor regularly so you can be monitored closely throughout your treatment.</li><li>• Seek medical advice immediately if you develop any of the symptoms of ovarian hyperstimulation listed in this leaflet.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use ELONVA if you are pregnant or breastfeeding.</li><li>• Do not use ELONVA if you have enlarged ovaries or ovarian cysts, recent unexpected vaginal bleeding where the cause is unknown, have cancer of the ovary, breast, uterus, pituitary gland or hypothalamus, have primary ovarian failure, fibroid tumours in the uterus or malformations of the sexual organs which make normal pregnancy impossible.</li><li>• Do not use ELONVA if you have risk factors for Ovarian Hyperstimulation Syndrome (OHSS).</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ELONVA affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• You can store ELONVA in the refrigerator (2°C to 8°C) until the expiry date. (Do not freeze).</li><li>• ELONVA can also be stored at or below 25°C for a total 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</li></ul>

For more information, see Section [5. What should I know while using ELONVA?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include headache, nausea, pelvic discomfort or pain, fatigue and breast tenderness. Serious side effects include severe allergic reactions and ovarian hyperstimulation syndrome (OHSS).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ELONVA®

Active ingredient(s): *Corifollitropin alfa (rch)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ELONVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ELONVA.**

**Where to find information in this leaflet:**

- [1. Why am I using ELONVA?](#)
- [2. What should I know before I use ELONVA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ELONVA?](#)
- [5. What should I know while using ELONVA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using ELONVA?

ELONVA contains the active ingredient **corifollitropin alfa, a medicine belonging to the group of gonadotrophic hormones**. These hormones play an important part in human fertility and reproduction. One of these gonadotrophic 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 participating in in vitro fertilisation (IVF).

**ELONVA is used to help achieve pregnancy in women having infertility treatment, such as IVF.**

ELONVA causes the growth and development of several follicles at the same time by controlled stimulation of the ovaries. The eggs are collected from the ovary, fertilised in the laboratory and the embryos are transferred into the uterus a few days later.

ELONVA is not addictive.

### 2. What should I know before I use ELONVA?

#### Warnings

**Do not use ELONVA if:**

- you are allergic to corifollitropin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- are pregnant or think you may be pregnant.
- are breastfeeding.
- have cancer of the ovary, breast, uterus, or brain (pituitary gland or hypothalamus).
- have recently had unexpected vaginal bleeding (other than periods) where the cause is unknown.

- 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 tumours 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
- if the syringe or needle is damaged
- if the solution is not clear
- if the packaging is torn or shows signs of tampering

**Check with your doctor if you:**

- have any other medical conditions (for example, diabetes, heart disease, or any other long-term disease)
- have ever had ovarian hyperstimulation syndrome (OHSS)
- are pregnant or think you might be pregnant
- have ever had stomach (abdominal) surgery
- have ever had a twisting of an ovary (ovarian torsion). Twisting of an ovary could cause the blood flow to the ovary to be cut off.
- have past or current cysts in your ovary or ovaries
- have kidney disease
- have uncontrolled pituitary gland or hypothalamic problems
- have an underactive thyroid (hypothyroidism)
- have adrenal glands that are not working properly (adrenocortical insufficiency)
- have high prolactin levels in the blood (hyperprolactinemia)
- have been told by a doctor that pregnancy would be dangerous for you
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## Ovarian Hyperstimulation Syndrome (OHSS)

Treatment with gonadotrophic 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.

OHSS causes fluid to build up suddenly in your stomach and chest areas and can cause blood clots to form.

### Call you 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 build up
- diarrhoea
- decreased urine output
- trouble breathing

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.

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

## Thrombosis (blood clot)

Treatment with gonadotrophic hormones like ELONVA may (as in 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

## Multiple pregnancies

In women having fertility treatment, the risk of multiple pregnancies (having twins or even more than two babies) is mainly related to the number of embryos 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.

## 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 tumours

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

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ELONVA.**

## 4. How do I use ELONVA?

Treatment with ELONVA should be started under the supervision of a specialist doctor experienced in fertility treatment.

### How much to inject

- 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.
- Your doctor may also give you other medication (such as a GnRH antagonist) to prevent early release of eggs from your ovary.

### When to inject ELONVA

- Your doctor will explain exactly when to give the injection.
- Seven days after the injection of ELONVA, your doctor may decide to continue your treatment cycle with another gonadotrophic hormone, like follicle-

stimulating hormone (FSH) medicine. This may be continued for a few days until enough follicles of adequate size are present. This can be checked by ultrasound examination. FSH treatment is then stopped and the eggs are matured by giving hCG (human Chorionic Gonadotrophin).

- The eggs are collected from the ovary 34-36 hours later.

### How to inject ELONVA

- ELONVA must be injected under the skin (subcutaneous) into a skin fold (that you pinch between your thumb and index finger), preferably just below the navel.
- **Do not inject ELONVA into a muscle.**
- The doctor or nurse may give you the injection.
- ELONVA can also be injected by yourself or by your partner.
- If the doctor decides you can give the injection yourself, the doctor or nurse will teach you the injection technique.
- A step-by-step "instructions for use" is given at the end of this leaflet.
- **Do not attempt self-injection until you are sure of how to do it.**
- Your partner may be trained to give the injection at home.
- ELONVA is supplied in pre-filled syringes that have an automatic safety system to help prevent needle stick injuries after use.

### If you forget to inject ELONVA

Contact your doctor immediately if you forget to inject ELONVA on the day you should have. Do not inject ELONVA without talking to your doctor.

### If you use too much ELONVA (overdose)

Contact your doctor immediately 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.

## 5. What should I know while using ELONVA?

Your doctor will carefully monitor your response using ultrasound scans of your ovaries during treatment with ELONVA. Your doctor may also check blood hormone levels.

### Things you should do

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

**If you plan to have surgery, tell your doctor or dentist that you are using ELONVA.**

A possible complication of treatment with gonadotrophic 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 serious medical condition called ovarian hyperstimulation syndrome (OHSS). Signs and symptoms of severe OHSS may include:

- acute stomach pain, weight gain, shortness of breath and passing less urine.
- in rare cases blood clots. Signs of a blood clot include pain, warmth, redness, numbness or tingling in your arm or leg.

**Call your doctor straight away or go to the accident and emergency at your nearest hospital if you have stomach pains or any of the other symptoms of ovarian hyperstimulation, even if they happen some days after the injection has been given.**

Remind any doctor, dentist or pharmacist you visit that you are using ELONVA.

### Things you should not do

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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ELONVA affects you.**

ELONVA may cause dizziness. If you feel dizzy, you should not drive a car, operate machinery or do anything else that could be dangerous.

### Looking after your medicine

- Store ELONVA in the refrigerator (2°C to 8°C) until the expiry date. Do not freeze. OR Store at or below 25°C for a total 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 until you are ready to use it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## When to discard your medicine

### 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.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not dispose of an empty or unused syringe in household waste.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>• Feeling sick (nausea)</li> <li>• Abdominal distension</li> <li>• Vomiting</li> <li>• Diarrhoea</li> <li>• Constipation</li> </ul> <b>Head and nervous system-related:</b> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Dizziness</li> </ul>	<b>These side effects are not usually serious but can become serious. Seek immediate medical care if you have any concerns.</b>

Less serious side effects	What to do
<b>Reproductive system or breast-related:</b> <ul style="list-style-type: none"> <li>• Pelvic discomfort or pain</li> <li>• Breast tenderness</li> <li>• Releasing an egg too early (premature ovulation)</li> <li>• Breast pain</li> </ul> <b>Procedure-related:</b> <ul style="list-style-type: none"> <li>• Pain after oocyte retrieval</li> <li>• Procedural pain</li> </ul> <b>Mood-related:</b> <ul style="list-style-type: none"> <li>• Irritability</li> <li>• Mood swings</li> </ul> <b>Muscle/skeleton-related:</b> <ul style="list-style-type: none"> <li>• Back pain</li> </ul> <b>General conditions:</b> <ul style="list-style-type: none"> <li>• Tiredness (fatigue)</li> <li>• Bruising or pain at the injection site</li> </ul> <b>Heart and circulation-related:</b> <ul style="list-style-type: none"> <li>• Hot flush</li> </ul> <b>Liver-related:</b> <ul style="list-style-type: none"> <li>• Liver enzyme increases</li> </ul>	<b>These side effects are not usually serious but can become serious. Seek immediate medical care if you have any concerns.</b>

### Serious side effects

Serious side effects	What to do
<b>Allergic Reaction:</b> <ul style="list-style-type: none"> <li>• rash, itching or hives on the skin</li> <li>• swelling of the face, lips, tongue or other parts of the body</li> <li>• shortness of breath, wheezing or difficulty breathing</li> </ul> <b>Ovarian Hyperstimulation Syndrome (OHSS):</b> <ul style="list-style-type: none"> <li>• severe abdominal swelling and pain in the stomach area (abdomen)</li> <li>• feeling sick (nausea)</li> <li>• vomiting</li> <li>• sudden weight gain due to fluid build up</li> <li>• diarrhoea</li> <li>• decreased urine output</li> <li>• trouble breathing</li> </ul> <b>Rare complications of OHSS:</b> <ul style="list-style-type: none"> <li>• blood clots (thromboembolism)</li> <li>• twisting of the ovaries (ovarian torsion)</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects, even if a few days have passed since your last injection, or you have stopped using ELONVA.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

Organon New Zealand Limited  
Level 7, 36 Brandon Street  
Wellington 6011  
New Zealand

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## 7. Product details

This medicine is only available with a doctor's prescription.

### What ELONVA contains

<b>Active ingredient (main ingredient)</b>	corifollitropin alfa (rch)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium citrate dihydrate</li><li>• sucrose</li><li>• polysorbate 20</li><li>• methionine</li><li>• water for injections</li><li>• sodium hydroxide and/or hydrochloric acid for adjustment of pH.</li></ul> ELONVA contains less than 1 mmol sodium (23 mg) per injection, i.e. essentially "sodium-free".
<b>Potential allergens</b>	ELONVA does not contain latex

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ELONVA looks like

ELONVA is a clear and colourless solution in a pre-filled syringe for single use.

The syringe has an automatic safety system, which prevents needle stick injuries after use.

ELONVA is supplied in two strengths:

- Pre-filled syringe containing 100 micrograms of corifollitropin alfa in 0.5 mL (AUST R 160646)
- Pre-filled syringe containing 150 micrograms of corifollitropin alfa in 0.5 mL (AUST R 160645)

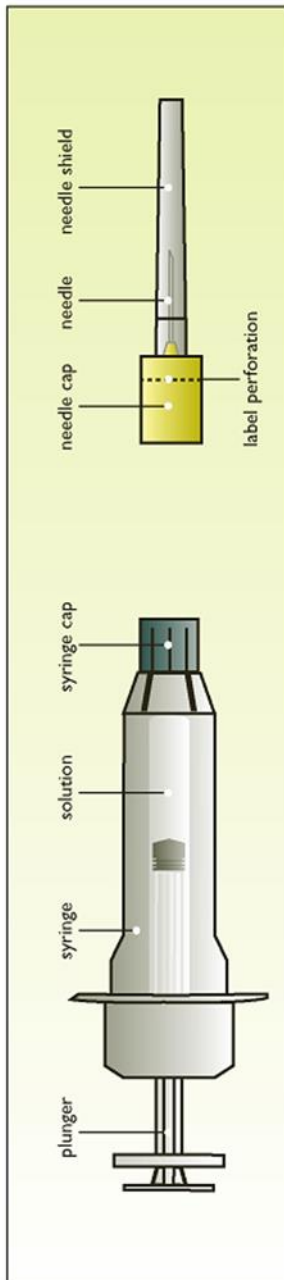
ELONVA is available in packs containing 1 pre-filled syringe and a sterile injection needle

### Who distributes ELONVA

Organon Pharma Pty Ltd  
Level 5, 66 King St  
Sydney NSW 2000  
Australia

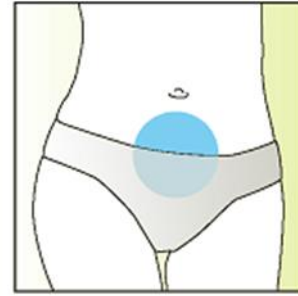
## 8. Instructions for use

Components of the ELONVA syringe with needle:



### Preparing the injection

1.

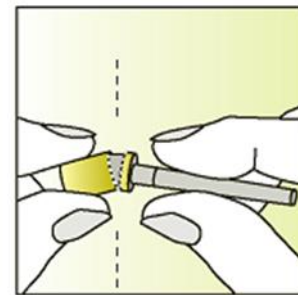


Wash your hands with soap and water and dry them before you use ELONVA.

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.



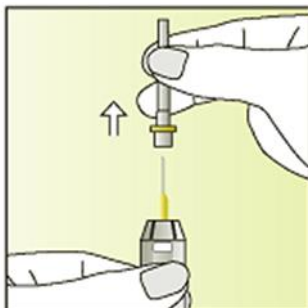
Keep the syringe pointing upwards.  
Unscrew the syringe cap counter-clockwise.

5.



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

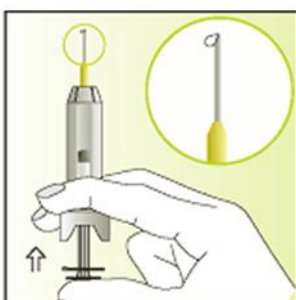
6.



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

### **Injecting**

7.

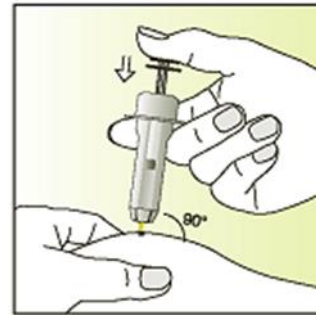


Now take the syringe between index and middle finger in the upward position.

Place your thumb on the plunger.

Carefully push the plunger upwards until a tiny droplet appears at the tip of the needle.

8.

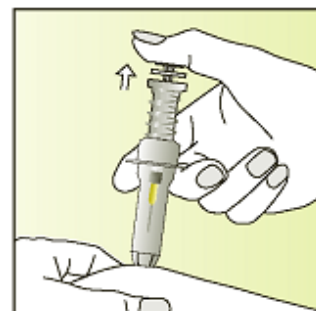


Pinch a fold of the skin between thumb and index finger.  
Insert the entire needle at an angle of 90 degrees into the fold of the skin.

**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.