

ELONVA[®]

Corifollitropin alfa (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Elonva.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Elonva against the benefits they expect it will have for you.

If you have any concerns about using this medicine, tell your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What Elonva is used for

Elonva contains 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 eggs in the ovaries.

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 of several eggs 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 back into the womb a few days later.

Elonva is not addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use Elonva

When you must not use it

Do not use Elonva if you:

- are allergic (hypersensitive) to corifollitropin alfa or to any of the ingredients in Elonva listed at the end of this leaflet
- have cancer of the ovary, breast, womb, or brain (pituitary gland or hypothalamus)
- are pregnant or breast feeding
- 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 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 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 your 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

Do not use Elonva:

- if the syringe or needle is damaged
- if the solution is not clear
- if the packaging is torn or shows signs of tampering
- after the expiry date printed on the pack has passed

If it has expired or is damaged, return it to your pharmacist or clinic.

If you are not sure whether you should start using Elonva, talk to your doctor.

Before you start to use it

Take special care with Elonva

Before starting to use this medicine, tell your doctor if you:

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

Your risk of having OHSS may increase if the dose of Elonva is too high.

Use Elonva only once during the same treatment cycle.

Ovarian Hyperstimulation Syndrome (OHSS).

Treatment with gonadotrophic 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, feeling sick or diarrhoea. Contact your doctor immediately if you have stomach pains or any of the other symptoms of OHSS, even if this happens

some days after the injection has been given.

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 Side Effects).

Thrombosis (blood clot)

Treatment with gonadotrophic hormones like Elonva may (as in 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 pregnancies. 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).

Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

How to use Elonva

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

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

How much to inject

If your body weight is 60kg or lower: Elonva 100 micrograms is given as a single injection on one of the first days of your period.

If your body weight is more than 60kg: Elonva 150 micrograms is given as a single injection on one of the first days of your period.

Your doctor will explain exactly when to give the injection.

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

Seven days after the injection of Elonva, your doctor may decide to continue treatment with another gonadotrophic hormone, like follicle-stimulating hormone (FSH) medicine. This may be continued for a few days until enough eggs 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 must be injected under the skin (subcutaneous) into a skin fold, just below the navel.

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.

If you forget to inject Elonva

Contact your doctor immediately if you forget to inject Elonva on the day you should have.

If you use too much (overdose)

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.

While you are using Elonva

Your doctor will carefully monitor your response using ultrasound and blood tests before and during treatment with Elonva.

Things you must do

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Elonva.

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

Tell all doctors and dentists who are treating you that you are using Elonva.

Things you must not do

Be careful driving or operating machinery 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.

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

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Elonva.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Common (affects 1 to 10 users in 100):

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

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

- Ovarian torsion (twisting of the ovary resulting in extreme lower stomach pain)
- Dizziness
- Vomiting
- Pain in the stomach
- Intestinal complaints (such as diarrhoea, constipation and swollen stomach)

A possible complication of treatment with gonadotrophic hormones like Elonva is unwanted overstimulation of the ovaries. The first symptoms of ovarian overstimulation may be: pain in the stomach, 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.

Tell your doctor immediately 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.

The following side effects are considered to be related to the Assisted Reproductive Technology (ART) program or subsequent pregnancy.

- miscarriage
- ectopic pregnancy (pregnancy that occurs outside the womb)
- multiple pregnancies

The incidence of congenital malformations (a physical defect present in a baby at birth) after ART may be slightly higher than after spontaneous conceptions. The slightly higher incidence is thought to be due to differences in patients undergoing fertility treatment (e.g age of the female, sperm characteristics) and to the higher incidence of multiple pregnancies after ART.

Tell your doctor if you notice anything that is making you feel unwell. Other side effects not listed above may occur in some patients.

After using it

Storage

Store Elonva in the refrigerator (2°C – 8°C). Do not freeze. Do not use after the expiry date on the carton.

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 until you are ready to use it.

Keep Elonva in a safe place away from the sight and reach of children.

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.

Disposal

Do not dispose of an empty or unused syringe in household waste. Ask your pharmacist or doctor how to dispose of medicines no longer required. These measures will help protect the environment.

Product description

What it 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.

One pre-filled syringe contains 100 micrograms or 150 micrograms of corifollitropin alfa in 0.5 mL.

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

Ingredients

Active ingredient

- corifollitropin alfa (rch)

Inactive ingredients

- sodium citrate
- sucrose
- polysorbate 20
- methionine
- water for injections

- sodium hydroxide and/or hydrochloric acid for adjustment of pH.

Elonva contains less than 1 mmol sodium (23 mg) per injection, i.e essentially “sodium-free”.

Supplier

Schering-Plough Pty Limited
Level 4, 66 Waterloo Road
North Ryde NSW 2113
Australia

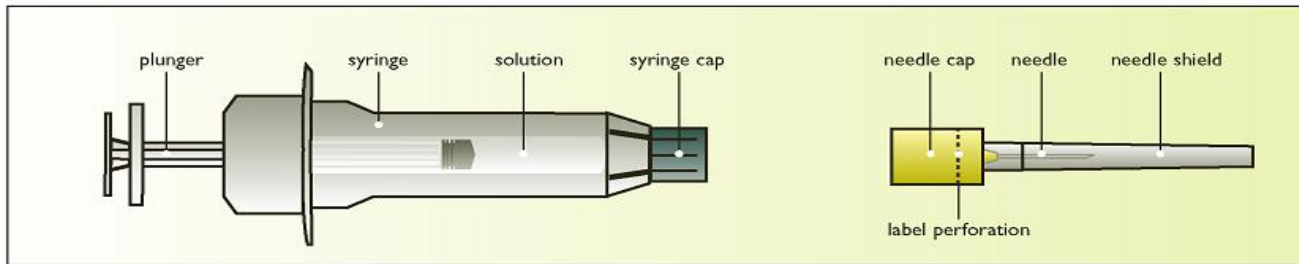
Australian Registration Numbers:
AUST R 160646 (100 µg/0.5 mL)
AUST R 160645 (150 µg/0.5 mL)

Schering-Plough, a division of
Schering-Plough Animal Health
Limited
36 Kitchener Street
Auckland

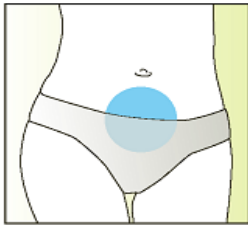
Date of preparation: July 2010

Instructions for use

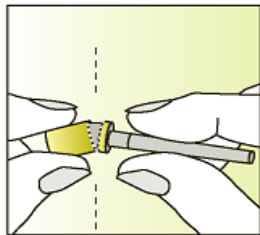
Components of the Elonva syringe with needle



Preparing the injection



1. Clean the skin area where the needle will enter with a disinfectant.



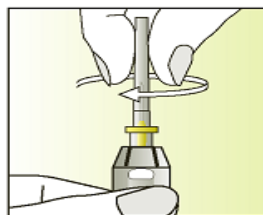
2. Break the label perforation and pull off the needle-cap
Leave the needle shield on the needle
Place the needle shield (containing the needle) on a clean dry surface, while preparing the syringe.



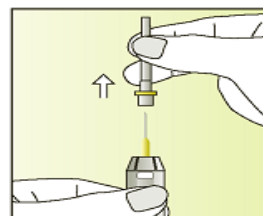
3. Hold the syringe with the grey cap pointing upwards
Tap the syringe gently with your finger to help air bubbles rise to the top.



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

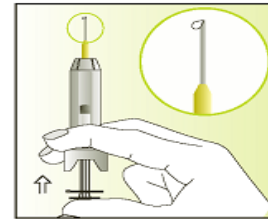


5. Keep the syringe pointing upwards
Screw the needle shield (containing the needle) clockwise onto the syringe.

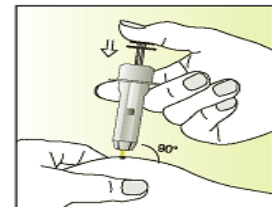


6. Keep the syringe pointing upwards
Remove the needle shield straight up and discard it
BE CAREFUL with the needle

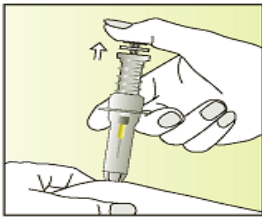
Injecting



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.