

GONAL-f® PEN

Recombinant human follicle stimulating hormone (follitropin alfa [rch])

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GONAL-f.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using GONAL-f against the benefits it is expected to have for you.

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

Keep this information with your medicine.

You may need to read it again later.

What is GONAL-f used for

GONAL-f contains follitropin alfa, which is similar to follicle stimulating hormone (FSH) found naturally in humans.

GONAL-f belongs to a class of hormones called gonadotrophins. FSH is necessary for the growth and development of egg cells (follicles) in women, and sperm production in men.

In women

GONAL-f can be used to bring about the development of follicles in women who are not ovulating and who have not responded to treatment with clomiphene citrate.

GONAL-f is also used to stimulate the development of several follicles in women undergoing assisted reproductive technologies (ART) such as in vitro fertilisation (IVF).

In men

GONAL-f is used in combination with human chorionic gonadotrophin (hCG) to stimulate the production of sperm.

Ask your doctor if you have any questions about why GONAL-f has been prescribed for you.

Your doctor may have prescribed it for another reason.

GONAL-f is available only on a doctor's prescription.

GONAL-f is not habit-forming.

Before you are given GONAL-f

When you must not use GONAL-f

Do not use GONAL-f if you have a history of allergy to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use GONAL-f if you have tumours of the hypothalamus or pituitary gland.

For women

Do not use GONAL-f if:

- you are pregnant
- you are breastfeeding
- your ovaries are enlarged
- you have an unexplained ovarian cyst
- you have unexplained vaginal or uterine bleeding
- you have cancer of the ovaries, uterus or breasts
- your ovaries have failed
- you have fibroids in your uterus which would make pregnancy impossible

For men

Do not use GONAL-f if:

- you have increased levels of gonadotrophins indicating failure of the testes
- your infertility is due to disorders other than hypogonadotrophic hypogonadism (low levels of gonadotrophins)

If you are not certain whether these conditions apply to you, or you are worried about anything on this list, tell your doctor.

Do not give this medicine to a child or elderly person.

Do not use this medicine after the expiry date (month/year) on the packaging has passed, or if the packaging is torn or shows signs of tampering.

If your medicine has expired or is damaged, return it to your pharmacist / clinic for disposal.

If you are not sure whether you should start using GONAL-f, talk to your doctor.

Before you start to use GONAL-f

Your doctor will assess you and your partner's fertility. This may include tests for other medical conditions, which may interfere with your ability to become pregnant. If necessary, other medical conditions may be treated before starting infertility treatments including GONAL-f.

Tell your doctor if you have any allergies to any foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have had any of the following medical conditions:

- disorders of the thyroid gland
- disorders of the adrenal glands
- high prolactin levels in the blood
- porphyria or a family history of porphyria

For women

Your doctor will assess if you have any medical conditions which interfere with your ability to become pregnant.

Treatment with GONAL-f may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries over-react to the hormonal treatment and become larger.

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by the use of ultrasound and/or blood tests to help determine if you are likely to develop OHSS. If necessary your doctor will delay or cancel your GONAL-f injection. You may also be advised to refrain from sexual intercourse until the end of the cycle if this occurs.

Compared to natural conception, the frequency of multiple pregnancies and births is higher in patients receiving treatments that stimulate follicle growth for ovulation induction. The majority of these are twins. Your doctor will monitor your response to treatment to minimise the chance of multiple pregnancies, because of the greater risks they carry for mothers and babies.

Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing treatments to stimulate follicle growth for ovulation induction.

There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedures. An effect of medicines used to induce ovulation has not been excluded.

Tell your doctor if you or a family member have or have had signs of blood clots (e.g. pain, warmth, redness, numbness or tingling in the arm or leg).

Treatment with GONAL-f and hCG may increase the risk of blood clots forming in your blood vessels.

Talk to your doctor about any concerns you may have before undergoing treatment or before you start using GONAL-f.

For men

Elevated FSH blood levels are indicative of testicular failure. Your doctor may ask you for a semen analysis to assess your response to treatment.

Talk to your doctor about any concerns you may have before you start using GONAL-f

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines

- **any medicines, vitamins, herbal supplements or natural therapies you buy without prescription from your pharmacy, supermarket, naturopath or health food shop**

Some medicines may be affected by GONAL-f or may affect how well it works.

Your doctor has more information on medicines to be careful with or avoid while using GONAL-f.

How GONAL-f is given

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

They may differ from the information contained in this leaflet.

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

GONAL-f is given as a course of daily injections.

You should have your injection at the same time each day.

How much to inject

Your doctor will decide the correct dose of GONAL-f for you. Your dose of GONAL-f may be adjusted depending on your individual response to treatment. Please consult your doctor if you are in any doubt.

The following is a guide to the common dose.

1. **Women who are not ovulating**
The common dose usually starts at 75IU (5.46 microgram) daily. The dose may be adjusted as your treatment progresses. The maximal daily dose is usually not higher than 225 IU (16.5 microgram).

2. **Women undergoing assisted reproductive technologies**
The common dose usually starts at 150 IU (10.92 microgram) daily, commencing on day 2 or 3 of the cycle. The dose may be adjusted as your treatment progresses. The maximal daily dose is usually not higher than 450 IU (32.76 microgram).
3. **Men with hypogonadotropic hypogonadism**
GONAL-f is commonly given with hCG. The common dose usually starts at 150 IU (10.92 microgram) three times a week.

How to inject

GONAL-f is given as a subcutaneous (under your skin) injection in the lower abdominal area or thigh.

GONAL-f is intended to be injected by you or your partner.

Alternatively your doctor or a nurse may give you these injections.

If your doctor or nurse decides you can give the injections yourself, the doctor or nurse will teach you the injection technique.

Do not self-inject until you are sure of how to do it.

Read the Instructions for Use provided in the pack carefully before commencing injections.

Your partner may be trained to give the injection at home.

Where to inject

GONAL-f is usually given in the lower abdominal area (except around the navel and waistline) or the front of your thigh. The injection site should be changed daily to lessen possible injection site reactions.

Do not inject into any areas in which you feel lumps, firm knots, depressions, pain, or see any discolouration.

Talk to your doctor if you find anything unusual when injecting.

How long to use GONAL-f for

For women

The length of treatment varies with each patient. It is possible to have more than one treatment cycle of GONAL-f.

For men

The combination treatment of GONAL-f and hCG could continue for at least 4 months and may continue for up to 18-24 months.

If you forget to inject GONAL-f

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject a double dose on any day.

Ask your doctor if you are not sure what to do or have trouble remembering to inject your medicine.

If you injected too much

Immediately contact your doctor or the Poisons Information Centre (In Australia telephone 131 126. In New Zealand telephone 0800 764 766) if you are concerned that you have given yourself too much or someone else has injected themselves with GONAL-f.

While you are using GONAL-f

Your doctor will carefully monitor your response to GONAL-f by using ultrasound, blood tests or semen analysis.

Things you must do

See your doctor regularly.

Your doctor will monitor you closely throughout your treatment.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using GONAL-f.

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

Tell all doctors, dentists and pharmacists who are treating you that you are using GONAL-f.

For Women

Tell your doctor immediately if you become pregnant while using GONAL-f.

Things you must not do

If you are self-injecting do not:

- **Stop using GONAL-f without telling your doctor.**
- **Change the dose unless your doctor tells you to.**
Changing your dose without advising your doctor can increase your risk of unwanted side effects or can prevent the drug from working properly.
- **Give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.**

Things to be careful of

Be careful driving or operating machinery until you know how GONAL-f affects you.

Side Effects

Tell your doctor as soon as possible if you do not feel well while using GONAL-f.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop using GONAL-f without first talking to your doctor.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of an allergic reaction, including swelling of the face, lips, tongue, or other parts of the body; shortness of breath, wheezing or difficulty breathing; severe skin rash, itching or hives.

Tell your doctor if you notice any of the following and they worry you:

- pain, redness, itching or swelling at the site of injection during your treatment with GONAL-f

For women

- vaginal bleeding
- inflammation, swelling or pain in your legs
- signs of severe OHSS such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amounts of urine and shortness of breath
- warning signs of stroke or heart attack
- warning signs of blood clots such as pain, warmth, redness, numbness or tingling in your arm or leg

Ectopic pregnancy (embryo implanted outside the womb) may occur, especially in women with prior tubal disease.

Tell your doctor if you notice any of the following and they worry you:

- headache, dizziness
- stomach pain, abdominal distension or abdominal discomfort
- nausea, vomiting
- diarrhoea

For men

- acne
- some breast development
- weight gain

These are common side effects.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After Using GONAL-f

Storage

Prior to using, store GONAL-f PEN in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Should refrigeration be unavailable, the GONAL-f PEN can be stored below 25°C for up to 3 months and away from light.

After first piercing the GONAL-f PEN with a needle, GONAL-f PEN may be stored below 25°C for a maximum of 21 days with the cap on, in order to protect the product from light.

Do not use GONAL-f PEN if the solution contains particles or is not clear.

Do not use the product after the expiry date printed on the label.

Do not use GONAL-f if you notice any visible signs of deterioration or damage to the container.

Do not use GONAL-f on anyone else.

It is for your use only.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half-metres above the ground is a good place to store medicines.

Disposal

If you are self-injecting, you should discard all sharps into a disposal unit.

If you have any GONAL-f that has expired or is left over from your treatment refer this to your clinic.

Product description

What it looks like

GONAL-f PEN is available in three strengths of 300 IU (21.84 microgram), 450 IU (32.76 microgram) and 900 IU (65.52 microgram).

GONAL-f PEN is pre-filled with a clear, colourless solution of 0.5 mL (300 IU), 0.75 mL (450 IU) or 1.5 mL (900 IU).

Each cartridge contains the following ingredients:

Active ingredient

- Follitropin alfa
300 IU (21.84 microgram), 450 IU (32.76 microgram) or 900 IU (65.52 microgram)

Other ingredients

- Sucrose
- Sodium phosphate - dibasic dihydrate
- Sodium phosphate - monobasic
- Sodium hydroxide
- Phosphoric acid
- Poloxamer
- Methionine
- m-cresol
- Water for Injections

GONAL-f 300 IU/0.5 mL (21.84 microgram/0.5 mL) PEN is supplied in packs of:

1 cartridge pre-assembled in a disposable pen and 8 needles for administration.

GONAL-f 450 IU/0.75 mL (32.76 microgram/0.75 mL) PEN is supplied in packs of:

1 cartridge pre-assembled in a disposable pen and 12 needles for administration.

GONAL-f 900 IU/1.5 mL (65.52 microgram/1.5 mL) PEN is supplied in packs of:
1 cartridge pre-assembled in a disposable pen and 20 needles for administration.

Australian Registration Numbers:

- GONAL-f 300 IU PEN for injection
AUST R 96230
- GONAL-f 450 IU PEN for injection
AUST R 96236
- GONAL-f 900 IU PEN for injection
AUST R 96237

Supplier

GONAL-f PEN is supplied in Australia by:

Merck Serono Australia Pty Ltd
3-4/25 Frenchs Forest Road East
Frenchs Forest NSW 2086

For enquiries call:
1800 633 463

GONAL-f PEN is supplied in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks, Auckland

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