

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 GONAL-f?

GONAL-f contains the active ingredient follitropin alfa. In women, GONAL-f is 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. In men, GONAL-f is used in combination with human chorionic gonadotrophin (hCG) to stimulate the production of sperm.

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

2. What should I know before I use GONAL-f?

Do not use if you have ever had an allergic reaction to GONAL-f 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, are pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with GONAL-f 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 GONAL-f?

- Your doctor will decide the correct dose of GONAL-f for you. Your dose may be adjusted depending on your individual response to treatment.
- Follow all directions given to you by your doctor, nurse or pharmacist carefully, including the Instructions for Use provided in the pack. Do not self-inject until you are sure of how to do it.

More instructions can be found in Section [4. How do I use GONAL-f?](#) in the full CMI and in the Instructions for Use leaflet inside the pack.

5. What should I know while using GONAL-f?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using GONAL-f.• Tell your doctor immediately if you become pregnant while using GONAL-f.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without telling your doctor.• Do not give this medicine to anyone else even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• Prior to use, store GONAL-f in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Should refrigeration be unavailable, GONAL-f can be stored below 25°C for up to 3 months.• After first use, GONAL-f may be stored below 25°C for up to 21 days with the cap on to protect the product from light.

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

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. Most common side effects include injection site reactions, such as redness, pain and swelling at the site of injection. In women, common side effects may include headache, dizziness, abdominal pain, discomfort, nausea, vomiting and diarrhoea. In men, common side effects may include acne, weight gain and breast development.

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.

GONAL-f®

Active ingredient: follitropin alfa (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using GONAL-f. **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 GONAL-f.**

Where to find information in this leaflet:

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

1. Why am I using GONAL-f?

GONAL-f contains the active ingredient follitropin alfa (recombinant human follicle stimulating hormone). This hormone is similar to follicle stimulating hormone found naturally in humans, but it is made by means of biotechnology. Follicle stimulating hormone belongs to the family of hormones called gonadotrophins and is necessary for the growth and development of egg cells in women and sperm production in men.

In women, GONAL-f is 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.

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

2. What should I know before I use GONAL-f?

Warnings

Do not use GONAL-f if:

- you are allergic to follitropin alfa, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have tumours of the hypothalamus or pituitary gland.

In women, do not use GONAL-f if:

- you are pregnant
- you are breastfeeding
- your ovaries are enlarged

- you have 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.

In men, do not use GONAL-f if:

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

Check with your doctor if you:

- have or have had any other medical conditions, such as:
 - o thyroid problems
 - o adrenal problems
 - o high prolactin levels in the blood
 - o porphyria or a family history of porphyria.
- take any medicines for any other condition.

Tell your doctor if you or a family members 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.

Your doctor will assess you and your partner's infertility. 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 with GONAL-f.

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 while using GONAL-f.

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

Multiple pregnancies carry risks for mothers and babies. Compared to natural conception, the frequency of multiple pregnancies and births is higher in patients receiving treatments that stimulate follicle growth for ovulation induction. Your doctor will monitor your response to minimise the chance of multiple pregnancies.

Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing fertility treatments.

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 procedure.

For men

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

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.

Some medicines may interfere with GONAL-f and affect how it works.

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

4. How do I use GONAL-f?

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

How much to use

- Always use GONAL-f exactly as your doctor has told you. You should check with your doctor if you are unsure.
- Your doctor will decide the correct dose of GONAL-f for you depending on your condition.
- For women who are not ovulating, the common dose usually starts at 75 IU daily. The dose may be adjusted as your treatment progresses. The maximum daily dose is usually not higher than 225 IU.
- For women undergoing assisted reproductive technologies, the common dose usually starts at 150 IU daily. The dose may be adjusted as your treatment progresses. The maximum daily dose is usually not higher than 450 IU.
- For men, the common dose usually starts at 150 IU three times a week.
- Your dose may be adjusted depending on your individual response to treatment.
- Follow the instructions provided by your doctor or nurse carefully.

When to use GONAL-f

- Your doctor will tell you when to use GONAL-f. The length of your treatment will be determined by your doctor depending on your condition.

How to use GONAL-f

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

- The injection site should be changed daily to lessen possible injection site reactions.
- Before using GONAL-f, your doctor or nurse can teach you the injection technique. Your partner may be trained to give the injection at home.
- Read the Instructions for Use provided in the pack before commencing injections. Do not self-inject until you are sure of how to do it.

If you forget to use 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 double dose to make up for the dose you missed.

If you use too much GONAL-f

If you think that you have used too much GONAL-f, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using GONAL-f?

Things you should do

See your doctor regularly. Your doctor will monitor you closely throughout your treatment.

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

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

Remind any doctor, dentist or pharmacist you visit that you are using GONAL-f.

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor.
- Do not change the dose unless your doctor tells you to.
- Do not give this medicine to anyone else even if they have the same condition as you.

Ovarian Hyperstimulation Syndrome (OHSS)

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

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by using 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GONAL-f affects you.

GONAL-f may cause dizziness in some people.

Looking after your medicine

- Prior to use, store GONAL-f in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.
- Should refrigeration be unavailable, GONAL-f can be stored below 25°C for up to 3 months.
- After first use, GONAL-f may be stored below 25°C for up to 21 days with the cap on to protect the product from light.

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

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

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.

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 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
Injection site related: <ul style="list-style-type: none"> • pain, numbness, redness or swelling at the injection site. Gastrointestinal system related: <ul style="list-style-type: none"> • stomach pain, abdominal pain or discomfort • nausea, vomiting, diarrhoea. Nervous system related: <ul style="list-style-type: none"> • headache, dizziness. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
Reproductive system related: <ul style="list-style-type: none"> • vaginal bleeding • ovarian cyst • ovarian enlargement • ovarian hyperstimulation syndrome (OHSS). 	

Serious side effects

Serious side effects	What to do
Symptoms of allergic reactions: <ul style="list-style-type: none"> • 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. Respiratory system related: <ul style="list-style-type: none"> • signs of aggravation of asthma, such as coughing, wheezing, chest tightness and shortness of breath. Vascular related: <ul style="list-style-type: none"> • signs of blood clots such as pain, warmth, redness, numbness or tingling in your arm or leg. Reproductive system related: <ul style="list-style-type: none"> • signs of severe ovarian hyperstimulation syndrome such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amount of urine and shortness of breath. 	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.

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.

In New Zealand, you can report side effects to Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>.

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.

7. Product details

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

What GONAL-f contains

Active ingredient (main ingredient)	Follitropin alfa (rch)
Other ingredients (inactive ingredients)	Sucrose Dibasic sodium phosphate dihydrate Monobasic sodium phosphate monohydrate Sodium hydroxide Phosphoric acid Poloxamer Methionine Metacresol (as a preservative) Water for injections

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

What GONAL-f looks like

GONAL-f contains sterile solution for injection in a cartridge, pre-assembled in a pen.

GONAL-f solution for injection is available in the following strengths and pack sizes:

- GONAL-f follitropin alfa (rch) 300 IU/0.48 mL solution for injection cartridge pre-assembled in a pen (AUST R 96230)

The pack contains 1 cartridge of solution for injection pre-assembled in a pen and 8 needles for administration.

- GONAL-f follitropin alfa (rch) 450 IU/0.72 mL solution for injection cartridge pre-assembled in a pen (AUST R 96236).

The pack contains 1 cartridge of solution for injection pre-assembled in a pen and 12 needles for administration.

- GONAL-f follitropin alfa (rch) 900 IU/1.44 mL solution for injection pre-assembled in a pen (AUST R 96237).

The pack contains 1 cartridge of solution for injection pre-assembled in a pen and 16 needles for administration.

Who distributes GONAL-f

GONAL-f is supplied in Australia by:

Merck Healthcare Pty Ltd

Suite 1, Level 1, Building B

11 Talavera Road

Macquarie Park NSW 2113

E-mail: medinfo.australia@merckgroup.com

For enquiries call: 1800 633 463

GONAL-f is supplied in New Zealand by:

Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks, Auckland

E-mail: medinfo.australia@merckgroup.com

For enquiries call: 0800 426 252

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