

# GONAL-F<sup>®</sup> SOLUTION FOR INJECTION IN PRE-FILLED PEN

Follitropin alfa (11mcg/0.24ml, 22mcg/0.48ml, 33mcg/0.72ml, 66mcg/1.44ml)

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## What Gonal-F is used for

Gonal-F can be used to bring about the development of follicles (each follicle contains one egg) 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).

## How Gonal-F works

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.

## Before you use Gonal-F

### - *When you must not use it*

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

Do not use Gonal-F if you have tumours of the hypothalamus or pituitary gland (both are part of the brain).

Do not use Gonal-F if you:

- are pregnant
- are breastfeeding
- have enlarged ovaries
- have an unexplained ovarian cyst
- have unexplained vaginal or uterine bleeding
- have cancer of the ovaries, uterus or breasts
- have ovary failure

- have fibroids in your uterus or malformations of sexual organs which would make pregnancy impossible

### - *Before you start to use it*

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 (inability to breakdown porphyrin that can be inherited).

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

### Ovarian Hyper-Stimulation Syndrome (OHSS)

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.

### Multiple Pregnancies

Compared to natural conception, the frequency of multiple pregnancies and births is higher in people receiving

treatments that stimulate follicle growth for ovulation induction. The majority of these are twins. Your doctor will monitor your response to treatment to minimize the chance of multiple pregnancies, because of the greater risks they carry for mothers and babies.

### Miscarriage/Abortion

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

### Birth Defects

There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to differences in maternal age, sperm characteristics or multiple pregnancies.

### Blood Clot Disorders

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.

### - *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 to use Gonal-F

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 use

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 starting dose is usually individualised and may be adjusted in a stepwise manner. The daily dose should not exceed 225 IU.

If a person fails to respond adequately continuation of that treatment cycle should be evaluated and managed accordingly to the standard clinical practice.

#### 2. Women undergoing assisted reproductive technologies

The starting dose usually individualised and may be adjusted in a stepwise manner to not higher than 450 IU daily.

### - How to inject

The first injection of GONAL-F should be performed under direct medical supervision.

This is a multidose medicine intended for several injections.

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 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.

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.

### - When to use it

Your doctor will decide how much medicine you will take and how often.

### - How long to use it

The length of treatment varies with each individual. It is possible to have more than one treatment cycle of Gonal-F.

### - If you forget to use it

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 use too much (overdose)

Immediately contact your doctor if you are concerned that you have given yourself too much or someone else has injected themselves with Gonal-F. Nevertheless, there is a possibility that OHSS may occur.

## While you are using Gonal-F

### - 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.

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 medicine 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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. 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, irritation or swelling at the site of injection during your treatment with Gonal-F
- 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 in your arm or leg
- ectopic pregnancy (embryo implanted outside the womb) may occur, especially in women with prior tubal disease.
- headache, dizziness
- stomach pain, abdominal distension or abdominal discomfort

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nptra.gov.my](http://nptra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

#### Storage and Disposal of Gonal-F

##### - Storage

Store in a refrigerator (2°C-8°C). Do not freeze.

Before opening and within its shelf life, the medicinal product may be stored outside of the refrigerator at temperatures up to a maximum of 25°C for a single period of up to 3 months. The product must be discarded if it has not been used within these 3 months.

Keep the cap on the pen, in order to protect from light.

Once opened, the medicinal product should be stored between 2°C and 25°C for a maximum of 28 days.

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.

Keep this medicine where children cannot reach it.

##### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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 150 IU/0.24 ml

0.24 ml of clear colourless solution for injection in 3 ml cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay. Pack of one pre-filled pen and 4 needles to be used with the pen injection.

##### Gonal-F 300 IU/0.48 ml

0.48 ml of clear colourless solution for injection in 3 ml cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay. Pack of one pre-filled pen and 8 needles to be used with the pen for injection.

##### Gonal-F 450 IU/0.72 ml

0.72 ml of clear colourless solution for injection in 3 ml cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay. Pack of one pre-filled pen and 12 needles to be used with the pen for injection.

##### Gonal-F 900 IU/1.44 ml

1.44 ml of clear colourless solution for injection in 3 ml cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay. Pack of one pre-filled pen and 16 needles to be used with the pen for injection.

Not all pack sizes are marketed.

##### - Ingredients

- Active ingredient: Follitropin alfa
- Inactive ingredients: Poloxamer 188, Sucrose, Methionine, Sodium dihydrogen phosphate monohydrate, Disodium phosphate dihydrate, m-Cresol, concentrated Phosphoric acid (for pH adjustment), Sodium hydroxide (for pH adjustment), Water for injections

##### - MAL number:

MAL20112176AZ

#### Manufacturer

Merck Serono S.p.A, Via delle Magnolie 15 (Zona Industriale), I- 70026, Modugno (BA), Italy

#### Product Registration Holder

Merck Sdn Bhd (178145-V)  
B-23A-1, Level 23A,  
The Ascent Paradigm No.1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia

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26/05/2025

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