



Merck Serono



PACKAGE LEAFLET: INFORMATION FOR THE USER

GONAL-f

75 IU (5.5 micrograms) powder and solvent for solution for injection

Follitropin alfa

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What GONAL-f is and what it is used for
2. Before you use GONAL-f
3. How to use GONAL-f
4. Possible side effects
5. How to store GONAL-f
6. Further information
How to prepare and use the GONAL-f powder and solvent.

1. WHAT GONAL-f IS AND WHAT IT IS USED FOR

What GONAL-f is
GONAL-f contains a medicine called "follitropin alfa". Follitropin alfa is a type of "Follicle Stimulating Hormone" (FSH) which belongs to the family of chemicals called "gonadotropins". Gonadotropins are involved in reproduction and fertility.

2. BEFORE YOU USE GONAL-f

- You and your partner's fertility should be evaluated before the treatment is started by a doctor experienced in treating fertility disorders.
Do not use GONAL-f
If you are allergic (hypersensitive) to Follicle Stimulating Hormone or any of the other ingredients of GONAL-f listed in section 6.
If you have a tumor in your hypothalamus or pituitary gland (both are parts of the brain).
If you are a woman:
with large ovaries or sacs of fluids within the ovaries (ovarian cysts) of unknown origin.
with unexplained vaginal bleeding.
with cancer in your ovaries, womb or breasts.
with a condition that usually makes normal pregnancy impossible, such as ovarian failure (early menopause), or malformed reproductive organs.
If you are a man:
with damaged testicles that cannot be healed.
Do not use GONAL-f if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using this medicine.

3. HOW TO USE GONAL-f

Always use GONAL-f exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Using this medicine
GONAL-f is intended to be given by injection just under the skin (subcutaneously).
The first injection of GONAL-f should be given under supervision of your doctor.
Your doctor or nurse will show you how to inject GONAL-f before you start your menstrual cycle.
If you administer GONAL-f to yourself, please carefully read and follow the instructions at the end of this leaflet called "How to prepare and use the GONAL-f powder and solution".

4. POSSIBLE SIDE EFFECTS

Like all medicines, GONAL-f can cause side effects, although not everybody gets them.
The frequency of possible side effects listed below is defined using the following convention:
very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)

5. HOW TO STORE GONAL-f

Keep out of the reach and sight of children.
Do not use GONAL-f after the expiry date which is stated on the vial or the EXP. The expiry date refers to the last day of that month.
Do not store above 25°C.

6. FURTHER INFORMATION

What GONAL-f contains
The active substance is follitropin alfa.
Each vial contains 5.5 micrograms of follitropin alfa.
After preparation of the final solution for injection, there are 75 IU (5.5 micrograms) of follitropin alfa in each millilitre of solution.
The other ingredients are sucrose, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate, methionine, polysorbate 20, concentrated phosphoric acid and sodium hydroxide.
The solvent is water for injections.

7. OTHER INFORMATION

What GONAL-f looks like and contents of the pack
GONAL-f is presented as a powder and solvent which are used to prepare a solution for injection.
The powder is a white pellet in a glass vial.

developing OHSS, your doctor may give you one or two hCG in this treatment cycle and you may be told not to have sex or to use a barrier contraceptive method for at least four days.

Multiple pregnancy
When using GONAL-f, you have a higher risk of being pregnant with more than one child at the same time ("multiple pregnancy", mostly twins), than if you conceived naturally. Multiple pregnancy may lead to medical complications for you and your child. You can reduce the risk of multiple pregnancy by using the right dose of GONAL-f at the right times. When undergoing assisted reproductive technology the risk of having a multiple pregnancy is related to your age, the quality and the number of fertilised eggs or embryos placed inside you.

Misconception
When undergoing assisted reproductive technology or stimulation of your ovaries to produce eggs, you are more likely to have a miscarriage than the average woman.

Blood clotting problems (thromboembolic events)
If you had in the past or recently blood clots in the leg or in the lung, or a heart attack or stroke, or if those happened in your family, then you might have a higher risk that these problems occur or become worse with GONAL-f treatment.

Men with too much FSH in their blood
If you are a man, having too much FSH in your blood can be a sign of damaged testicles. GONAL-f usually does not work if you have this problem.

If your doctor decides on GONAL-f treatment, to monitor the treatment, they may ask you to provide semen for analysis 4 to 6 months after starting treatment.

Children
GONAL-f is not indicated for use in children.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained from your pet or your babies. You can reduce the risk of multiple pregnancy by using the right dose of GONAL-f at the right times. When undergoing assisted reproductive technology the risk of having a multiple pregnancy is related to your age, the quality and the number of fertilised eggs or embryos placed inside you.

If you use GONAL-f with other medicines which help ovulation (such as hCG or clomiphene citrate), this may increase the response of your follicles.
If you use GONAL-f at the same time as a gonadotropin-releasing hormone (GnRH) agonist or antagonist (these medicines reduce your sex hormone levels and stop you ovulating) you may need a higher dose of GONAL-f to produce follicles.

Pregnancy and breast-feeding
Do not use GONAL-f if you are pregnant or breast-feeding.

Driving and using machines
It is not expected that this medicine will affect your ability to drive and use machines.

Important information about some of the ingredients of GONAL-f
GONAL-f contains less than 1 mmol sodium (23 mg) per dose, therefore it is considered essentially "sodium-free".

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recombinant DNA technique, or 5,000 IU to 10,000 IU of hCG, 24 to 48 hours after the last GONAL-f injection.

In this case, 7 days. The dose may first stop you from ovulating but using a gonadotropin-releasing hormone (GnRH) agonist or antagonist. Then GONAL-f is started approximately two weeks after start of agonist treatment.
The GONAL-f and GnRH agonist are then both given until your follicles develop as desired. For example, after two weeks of GnRH agonist treatment, 150 to 225 IU GONAL-f is administered for 7 days. The dose is then adjusted according to your ovarian response. When GnRH antagonist is used, it is administered from the 5th or 6th day of GONAL-f treatment and continued until ovulation induction.

Men
The usual dose of GONAL-f is 150 IU (0.24 ml) together with hCG.
You will take these two medicines three times a week for at least 4 months.
If you have not responded to treatment after 4 months, your doctor may suggest that you continue using these two medicines for at least 18 months.

If you use more GONAL-f than you should
The effects of taking too much GONAL-f are unknown. Nevertheless, it could expect Ovarian Hyper-Stimulation Syndrome (OHSS) to occur, which is described in section 4. However the OHSS will only occur if hCG is also administered (see section 2, OHSS).

If you forget to use GONAL-f
If you forget to use GONAL-f, do not take a double dose to make up for a forgotten dose. Please talk to your doctor as soon as you notice that you have missed a dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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- The solvent is a clear colourless liquid in a 3.00 ml vial of solution, each containing 1 ml.
GONAL-f is supplied in packs of 1, 10 vials of powder with the corresponding number of solvent in a pre-filled syringe.

HOW TO PREPARE AND USE THE GONAL-f POWDER AND SOLVENT

- This section tells you how to prepare and use your GONAL-f powder and solvent.
Before starting the preparation, please read these instructions the whole way through first.
Give yourself the injection at the same time each day.

1. Wash your hands and find a clean area
It is important that your hands and the items you use be as clean as possible.
A good place is a clean table or kitchen surface.

2. Get together everything you need and lay them out:
1 pre-filled syringe containing the solvent (the clear liquid)
1 vial containing GONAL-f (the white powder)
1 needle for preparation
1 fine bore needle for injection under the skin

Not provided in the pack:
1 2.0 ml syringe
1 2.0 ml swabs
1 sharp container

3. Preparing the solution
Remove the protective caps from the powder vial and from the pre-filled syringe.
Attach the needle for preparation to the pre-filled syringe, insert it into the powder vial and slowly inject all the solvent into the gently without removing the syringe. Do not shake.

Check that the resulting solution is clear and does not contain any particles.
Turn the vial upside down and gently draw the solution back into the syringe by pulling the plunger.

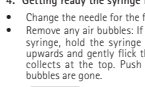
Remove the syringe from the vial and set it down carefully. Do not touch the needle and do not allow the needle to touch any surface.



If you have been prescribed more than one vial of GONAL-f, slowly re-inject the solution into another powder vial, until you have the prescribed number of powder vials dissolved in the solution. If you have been prescribed lutropin alfa in addition to GONAL-f, you may also mix the two medicines as an alternative to injecting each product separately. After dissolving the lutropin alfa powder, draw the solution back into the syringe and re-inject it into the vial containing GONAL-f. Once the powder has dissolved, draw the effect of the solution into the syringe. Inspect for particles as before, and do not use if the solution is not clear. Use of three containers of powder may be dissolved in 1 ml of solvent.

4. Getting ready the syringe for injection

Change the needle for the fine bore needle.
Remove any air bubbles: If you see air bubbles in the syringe, hold the syringe with the needle pointing upwards and gently flick the syringe until all the air collects at the top. Push the plunger until the air bubbles are gone.



5. Injecting the dose

Immediately inject the solution: Your doctor or nurse will have already advised you where to inject (e.g. tummy, front of thigh). To minimise skin irritation, select an area of skin for injection. Inspect for particles as before, and do not use if the solution is not clear. Use of three containers of powder may be dissolved in 1 ml of solvent.

Firmly pinch the skin together and insert the needle at a 45 to 90° angle using a dart-like motion.
Inject under the skin by pushing gently the plunger, as you were taught. Do not inject directly into the vein, as much time as you need to inject all the solution.

Immediately withdraw the needle and clean the skin with an alcohol swab using a circular motion.



6. After the injection

Dispose of all used items: Once you have finished your injection, immediately discard all needles and empty glass containers safely preferably in the sharp container. Any unused solution must be discarded.

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DATE OF INFORMATION

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For further inquiries inside Egypt, Call 16935

This is a medicine

A medicine is a product which affects your health and its consumption, contrary to instructions, is dangerous for you.
Inject under your doctor's prescription, the method of use and the instructions of the pharmacist who sold the product.
Your doctor and the pharmacist are experts in medicine and their benefits and risks.
Do not interrupt the period of treatment prescribed without your doctor's permission.
Do not repeat the same prescription without consulting your doctor.

Keep medicines out of reach of children.

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