

PATIENT INFORMATION
GONAL-F® (gon-AL-eff)
(follitropin alfa for injection)
for subcutaneous use

What is GONAL-F?

GONAL-F is a prescription medicine containing follicle-stimulating hormone (FSH).

GONAL-F is used in:

infertile women to:

- help healthy ovaries develop (mature) and release an egg to help you get pregnant
- cause your ovaries to make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) program

infertile men to:

- help develop and produce mature sperm

Do not use GONAL-F if you are a woman or man who:

- is allergic to recombinant human FSH or any of the ingredients in GONAL-F. See the end of this leaflet for a complete list of ingredients in GONAL-F.
- has a high level of FSH in your blood that show your ovaries (women only) or testes (men only) do not work at all.
- has uncontrolled thyroid, adrenal, or pituitary problems.
- has a tumor in your sex organs (uterus, ovaries, or testes) or breasts.
- has a tumor in your brain, such as a tumor in your pituitary gland or hypothalamus.

Do not use GONAL-F if you are a woman that :

- has abnormal bleeding from your uterus or vagina from an unknown cause.
- has ovarian cysts or large ovaries from an unknown cause

Before you start using GONAL-F, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had asthma
- have been told by a healthcare provider that you have an increased risk for blood clots (thrombosis)
- have ever had a blood clot (thrombosis), or anyone in your family has ever had a blood clot (thrombosis)
- have had stomach (abdominal) surgery

Before you start using GONAL-F and are a woman, tell your healthcare provider if you:

- have had twisting of your ovary (ovarian torsion)
- had or have a cyst on your ovary
- have polycystic ovarian disease
- are pregnant or think you may be pregnant. GONAL-F is not for pregnant women. Your healthcare provider will give you a pregnancy test before you start using GONAL-F.
- are breastfeeding. It is not known if GONAL-F passes into your breast milk. You and your healthcare provider should decide if you will take GONAL-F or breastfeed. You should not do both.
- are not an adult. GONAL-F is not for children. It is not known if GONAL-F is safe or works in children.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use GONAL-F?

- Read the "**Instructions for Use**" that comes with GONAL-F for information about the right way to use GONAL-F.
- Use GONAL-F exactly as your healthcare provider tells you to.
- GONAL-F is given by injection under your skin. You can inject GONAL-F under the skin in your stomach (abdomen), upper arm, or upper leg.
- **Do not** inject GONAL-F at home until your healthcare provider has taught you the right way to inject it.
- Change your injection site as your healthcare provider showed you.
- **Do not** change your dose or the time you are scheduled to use GONAL-F unless your healthcare provider tells you to.
- If you miss or forget to take a dose, do not double your next dose. Ask your healthcare provider for instructions.
- Your healthcare provider will do blood and urine hormone tests while you are using GONAL-F. Make sure you follow-up with your healthcare provider to have your blood and urine tested when told to do so.
- Call your healthcare provider if you have any questions about your dose or how to use GONAL-F.

Women:

- Your healthcare provider may do ultrasound scans of your ovaries. Make sure you follow-up with your healthcare provider to have your ultrasound scans.

Men:

- Your healthcare provider may test your semen while you are using GONAL-F. Make sure you follow-up with your healthcare provider to give a semen sample for testing.

What are the possible side effects of GONAL-F®?

GONAL-F may cause serious side effects in women and men, including:

- **severe allergic reactions.** Women or men who have used GONAL-F in the past may have a severe allergic reaction right away when they use GONAL-F again. This severe allergic reaction may lead to death. If you have any of the following symptoms of a severe allergic reaction, stop using GONAL-F and go to the nearest hospital emergency room right away:
 - shortness of breath
 - swelling of your face
 - itchy, red bumps or rash on your skin (hives)
- **lung problems.** GONAL-F may cause serious lung problems including fluid in your lungs (atelectasis), trouble breathing (acute respiratory distress syndrome), and worsening of asthma.
- **blood clots.** GONAL-F may increase your chance of having blood clots in your blood vessels. Blood clots can cause:
 - blood vessel problems (thrombophlebitis)
 - stroke
 - loss of your arm or leg
 - blood clot in your lung (pulmonary embolus)
 - heart attack

GONAL-F may cause serious side effects in women, including:

- **ovarian hyperstimulation syndrome (OHSS).** OHSS is both a serious and common side effect. Using GONAL-F may cause OHSS. OHSS is a serious medical condition that can happen when your ovaries produce too many eggs (overstimulated). OHSS can cause fluid to suddenly build up in the area of your stomach, chest, and heart, and can cause blood clots to form. In rare cases OHSS has caused death. OHSS may also happen after you stop using GONAL-F. Stop using GONAL-F and call your healthcare provider right away if you have symptoms of OHSS, including:
 - trouble breathing
 - nausea
 - diarrhea
 - severe lower stomach (pelvic) area pain
 - vomiting
 - decreased urine output
 - weight gain
- **twisting (torsion) of your ovary.** GONAL-F may increase the chance of your ovary twisting if you already have certain conditions such as OHSS, pregnancy and previous abdominal surgery. Twisting of your ovary may lead to blood flow being cut off to your ovary.
- **ovaries that are too large.** GONAL-F may cause your ovaries to be abnormally large. Symptoms of large ovaries include bloating or pain in your lower stomach (pelvic) area.
- **pregnancy with and birth of multiple babies.** GONAL-F may increase your chance of having a pregnancy with more than 1 baby. Having a pregnancy and giving birth to more than 1 baby at a time increases the health risk for you and your babies. Your healthcare provider should tell you about your chances of multiple births.
- **birth defects.** A baby born after an ART cycle may have an increased chance of having birth defects. Your chances of having a baby with birth defects may increase depending on:
 - your age
 - certain sperm problems
 - your genetic background and that of your partner
 - a pregnancy with more than 1 baby at a time
- **ectopic pregnancy (pregnancy outside your womb).** GONAL-F may increase your chance of having a pregnancy that is abnormally outside of your womb. Your chance of having a pregnancy outside of your womb is increased if you also have fallopian tube problems. Call your healthcare provider right away if you have symptoms of an ectopic pregnancy including:
 - stomach or pelvic pain especially on one side
 - neck pain
 - nausea and vomiting
 - shoulder pain
 - rectal pain

- **miscarriage.** Your chance of loss of an early pregnancy may be increased if you had difficulty becoming pregnant.
- **tumors of the ovary.** If you have used medicines like GONAL-F more than 1 time to get pregnant, you may have an increased chance of having tumors in your ovary(ies) (including cancer).

Common side effects of GONAL-F include:

in women:

- | | |
|----------------|----------------------------|
| • ovarian cyst | • headache |
| • OHSS | • stomach pain |
| • pelvic pain | • nausea |
| • gas | • bleeding between periods |

in men:

- | | |
|-----------------------|----------------------|
| • skin problems | • breast enlargement |
| • injection site pain | • seborrhea |
| • tiredness | |

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of GONAL-F. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GONAL-F?

- Before you use GONAL-F for the first time, store the vials:
 - in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date, or
 - store the vials at room temperature between 68°F to 77°F (20°C to 25°C) until the expiration date.
- After you use GONAL-F and there is still medicine left, store your vial in the refrigerator between 36°F to 46°F (2°C to 8°C) or at room temperature between 68°F to 77°F (20°C to 25°C) up to 28 days. Throw away any unused GONAL-F after 28 days.
- Store your GONAL-F vials in a safe place.
- Store GONAL-F away from light.

Keep GONAL-F and all medicines out of the reach of children.

General information about the safe and effective use of GONAL-F.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use GONAL-F for a condition for which it was not prescribed. Do not give GONAL-F to other people, even if they have the same condition that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about GONAL-F that is written for health professionals.

For more information, go to www.fertilitylifelines.com, or call 1-866-538-7879.

What are the ingredients in GONAL-F?

Active ingredient: follitropin alfa (r-hFSH)

Inactive ingredients: dibasic sodium phosphate dihydrate, monobasic sodium phosphate monohydrate, O-phosphoric acid, sodium hydroxide, sucrose.

EMD Serono, Inc

Rockland, MA 02370

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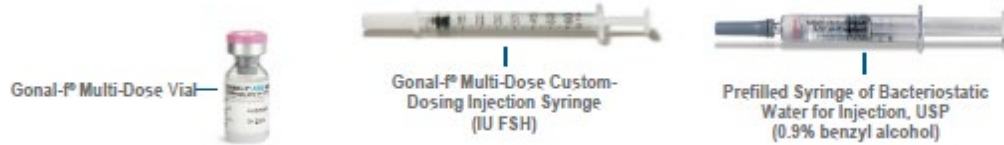
This Patient Package Insert has been approved by the U.S. Food and Drug Administration.

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Instructions for Use

GONAL-F®

(follitropin alfa for injection)
for subcutaneous use



Important

- **Read these instructions completely before you begin.**
- GONAL-F is for use under the skin only (subcutaneous).
- Only use GONAL-F if your healthcare provider trains you on how to use it correctly.

Warning:

- **Do not** reuse needles.
- **Do not** share your GONAL-F needles or syringes with another person. You may get a serious infection from other people or other people may get a serious infection from you.
- The syringes and needles that come with your GONAL-F are meant for use with GONAL-F only. **Do not** use GONAL-F syringes to inject other medicines or hormones.

Supplies needed to give your GONAL-F injection.

- a clean flat surface like a table
- 1 GONAL-F Multi-Dose vial
- 1 GONAL-F Multi-Dose Custom Dosing Injection Syringe
- 1 Prefilled Syringe of Bacteriostatic Water for Injection, USP
- 1 FDA-cleared sharps container
- 2 alcohol pads
- 1 gauze or cotton ball

Gather your supplies

- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- If the vial with the GONAL-F liquid mixed (reconstituted) solution is stored in the refrigerator, allow at least 30 minutes before you inject to let it warm to room temperature.



Caution: Do not use a microwave or other heating element to warm up the reconstituted liquid.

Step 1 Mixing (reconstituting)

- Wash your hands with soap and water.
- Using your thumb, flip off the plastic cap of the GONAL-F vial.



- Wipe the top of the vial stopper with an alcohol pad.



- Carefully twist and pull off the protective cap of the prefilled syringe of Bacteriostatic Water. Do not touch the needle or allow it to touch any surface.



- Hold the vial of GONAL-F powder firmly on a flat surface.
- Position the prefilled syringe of Bacteriostatic Water in a straight, upright position over the marked center circle of the rubber stopper on the vial of the GONAL-F powder.
- Insert the needle through the center circle of the rubber stopper on the vial of the GONAL-F powder while keeping it in a straight, upright position.



- Slowly inject the Bacteriostatic Water into the vial of GONAL-F powder by pressing down on the syringe plunger.



- Gently, rotate the vial between your fingers until the powder is dissolved. **Do not** shake.
- When all of the Bacteriostatic Water has been injected into the vial of GONAL-F powder, remove your finger from the syringe plunger and withdraw the needle from the vial. Immediately throw away (dispose of) the needle and syringe into your FDA-cleared sharps container (See Step 4: How to throw away used needles and syringes). Do not use this needle and syringe for your injection.



Step 2 Preparing the dose

- Check that the GONAL-F liquid solution is clear. Do not use if the liquid is discolored or contains any particles. If this happens, throw it away and call your healthcare provider or pharmacist right away.
- Allow the liquid solution to come to room temperature before giving your injection.
- Wipe the rubber stopper of the vial with an alcohol swab.
- Remove the wrapper and carefully, pull the needle cap off the Custom-Dosing Injection Syringe. **Do not** touch or allow the needle to touch any surface.

- Firmly hold the vial of GONAL-F liquid mixed (reconstituted) solution on a flat surface and insert the needle through the marked center circle of the rubber stopper.



- While keeping the needle in the vial, lift the vial and turn it upside down so that the needle points towards the ceiling.



- With the needle tip in the liquid, slowly pull back the plunger until the syringe fills to slightly more than the mark for your prescribed dose.



- Next, with the syringe pointing upward and keeping the needle in the vial, slowly push the syringe plunger to your prescribed dose and until all air bubbles are gone and a drop of liquid appears on the tip of the needle.



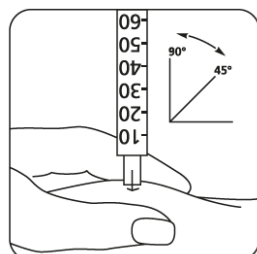
- Remove the syringe needle from the vial and recap the needle and set on a clean, flat surface.
- The syringe is now ready for giving your prescribed dose of GONAL-F.

Step 3 Injecting the dose

- Your healthcare provider should show you how to set the prescribed dose and use the syringe.
- Change your injection site each day to decrease discomfort. GONAL-F is injected under the skin (subcutaneously) of your stomach area, upper arm, or upper leg.



- Uncap the syringe and inject the prescribed dose as directed by your healthcare provider.



- Lightly press a cotton ball or gauze on the site if needed.

Step 4 How to throw away used needles and syringes

- Put used needles and syringes in an FDA-cleared sharps disposal container immediately after use.



Warning: Do not throw away loose needles in your household trash.

- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - Made of heavy-duty plastic,
 - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - Upright and stable during use,
 - Leak resistant, and
 - Properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
 - **Do not** reuse the needles
 - **Do not** throw way (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this.
 - **Do not** recycle your used sharps disposal container.

For more information, go to <http://www.fda.gov/safesharpsdisposal>.

Step 5 How to store your GONAL-F vials

- Store all vials with GONAL-F away from light.
- Store vials in the refrigerator between 36° F and 46° F (2°C and 8° C) until the expiration date, or at room temperature between 68° F and 77° F (20°C and 25°C) until the expiration date.
- If you have medicine left in a vial after injecting, store it in the refrigerator or at room temperature for a maximum of 28 days from the day the powder was mixed with Bacteriostatic Water. After 28 days, you must throw away (discard) your vial with unused solution.
- **Keep the GONAL-F vials and all medicines out of the reach of children.**

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