

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

**What is GONAL-F RFF?**

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

GONAL-F RFF 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

**Do not use GONAL-F RFF if you:**

- are allergic to recombinant human FSH or any of the ingredients in GONAL-F RFF. See the end of this leaflet for a complete list of ingredients in GONAL-F RFF.
- have high levels of FSH in your blood that show your ovaries do not work at all.
- have uncontrolled thyroid, adrenal, or pituitary problems.
- have a tumor in your female organs, including your ovaries, uterus or breast that may get worse with high levels of estrogen.
- have a tumor in your brain, such as a tumor in your pituitary gland or hypothalamus.
- have abnormal bleeding from your uterus or vagina from an unknown cause.
- have ovarian cysts or large ovaries from an unknown cause.

**Before you start using GONAL-F RFF 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
- 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 RFF is not for pregnant women. Your healthcare provider will give you a pregnancy test before you start using GONAL-F RFF.
- are breastfeeding. It is not known if GONAL-F RFF passes into your breast milk. You and your healthcare provider should decide if you will take GONAL-F RFF 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 RFF?

- Read the "**Instructions for Use**" that comes with GONAL-F RFF for information about the right way to use GONAL-F RFF.
- Use GONAL-F RFF exactly as your healthcare provider tells you to.
- GONAL-F RFF is given by injection under your skin. You can inject GONAL-F RFF under the skin in the stomach (abdomen), upper arm, or upper leg.
- **Do not** inject GONAL-F RFF 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 RFF 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 RFF. 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 RFF.
- Your healthcare provider may do ultrasound scans of your ovaries. Make sure you follow-up with your healthcare provider to have your ultrasounds.

### What are the possible side effects of GONAL-F RFF?

#### GONAL-F RFF may cause serious side effects, including:

- **severe allergic reactions.** Women who have used GONAL-F®, GONAL-F RFF or GONAL-F® Redi-Ject™ in the past may have a severe allergic reaction right away when they use GONAL-F RFF 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 RFF 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)
- **ovarian hyperstimulation syndrome (OHSS).** OHSS is both a serious and common side effect. Using GONAL-F RFF 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 RFF. Stop using GONAL-F RFF and call your healthcare provider right away if you have symptoms of OHSS, including:
  - trouble breathing      ○ severe lower stomach (pelvic) area pain      ○ weight gain
  - nausea      ○ vomiting
  - diarrhea      ○ decreased urine output
- **lung problems.** GONAL-F RFF 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 RFF 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
- **twisting (torsion) of your ovary.** GONAL-F RFF 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 RFF 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 RFF 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 RFF 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 RFF 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 RFF include:**

- |            |   |                    |
|------------|---|--------------------|
| • headache | • stomach pain                            | • stomach bloating |
| • OHSS     | • swelling and pain at the injection site | • diarrhea         |
| • nausea   | • gas                                     | • ovarian cyst     |

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 RFF. For more information, call 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 RFF?**

- Before you use GONAL-F RFF for the first time, store your vials:
  - in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date, or
  - store your vials at room temperature between 68°F to 77°F (20°C to 25°C) until the expiration date.
- After you use GONAL-F RFF throw away (discard) unused material.
- Store your GONAL-F RFF vials in a safe place.
- Store GONAL-F RFF away from light.

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

**General Information about the safe and effective use of GONAL-F RFF.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use GONAL-F RFF for a condition for which it was not prescribed. Do not give GONAL-F RFF 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 RFF that is written for health professionals.

**What are the ingredients in GONAL-F RFF?**

**Active ingredient:** follitropin alfa (r-hFSH)

**Inactive ingredients:** dibasic sodium phosphate dihydrate, methionine, monobasic sodium phosphate dihydrate, phosphoric acid and or sodium hydroxide, polysorbate 20, sucrose

For more information, go to [www.fertilitylifelines.com](http://www.fertilitylifelines.com), or call 1-866-538-7879.

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

12//2020

**Instructions for Use**  
**GONAL-F® RFF**  
(follitropin alfa injection)  
for subcutaneous use



**Important**

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

**Warning:**

- **Do not** reuse needles.
- **Do not** share your GONAL-F RFF 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 RFF are meant for use with GONAL-F RFF only. **Do not** use GONAL-F RFF syringes to inject other medicines or hormones.
- **The GONAL-F® RFF vial comes in only 75 International Units (IU)**

**Supplies needed to give your GONAL-F RFF injection.**

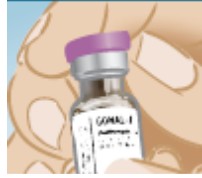
- a clean flat surface like a table
- 1 GONAL-F RFF 75 IU vial
- 1 Prefilled Syringe of Sterile Water for Injection, USP
- (1) 18 G 1 ½" Mixing Needle
- (1) 29 G ½" Injection Needle
- 1 FDA-cleared sharps container
- 2 alcohol pads
- 1 gauze or cotton ball

**Gather your supplies.**

- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.

**Step 1 Mixing (reconstituting)**

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



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



- Carefully twist and pull off the protective cap of the prefilled syringe of Sterile Water. **D**o not touch the needle or allow it to touch any surface.



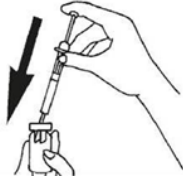
- Remove the safety seal cover of the 18 G 1 ½ " pink needle. Twist the needle onto the prefilled syringe until it is tightened, being careful to keep the protective needle cap in place. Carefully remove the protective needle cap. Do not touch or allow the needle to touch any surface.



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



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



- Gently, rotate the vial between your fingers until the powder is dissolved. **Do not** shake.
- While keeping the needle in the vial of GONAL-F RFF, lift and turn the vial upside down.
- With the needle tip in the liquid, slowly pull back the 18 G 1 ½ " pink needle as far as needed until you withdraw the entire contents of the vial. Remove the needle from the vial.



- Gently pull the plunger back to allow a small air space. Recap the needle.
- Twist off the 18 G 1 ½ " pink needle from the syringe and immediately throw away (dispose of) the needle in an FDA-cleared sharps disposal container (See Step 4: How to throw away used needles and syringes) unless you need to mix more vials to get your prescribed dose.
- **Do not** use this needle to give your injection.



**Note: If your dose requires more than 1 vial of GONAL-F RFF 75 IU, use the same 18 G 1 ½ " pink needle and syringe containing the mixture to mix (reconstitute) additional vials. Follow Step 1.**

## Step 2 Preparing the dose

- Check that the GONAL-F RFF 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.

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

- Remove the safety seal cover of the 29 G 1 ½ " red needle. Twist the needle onto the prefilled syringe until it is tightened, being careful to keep the protective needle cap in place. Carefully remove the protective needle cap. Do not touch or allow the needle to touch any surface
- With the syringe pointing upward, gently tap on the syringe and slowly push the plunger until all air bubbles are gone and a drop of liquid appears on the tip of the needle.



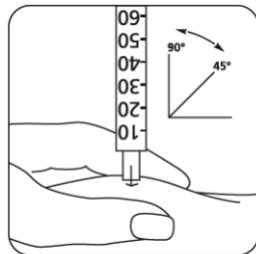
- Recap the needle and set on a clean, flat surface. The syringe is now ready for giving your prescribed dose of GONAL-F RRF.

### 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 RRF is injected under the skin (subcutaneously) of your stomach area, upper arm, or upper leg.



- Uncap the syringe and inject the 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 and pens in your household trash.**

- If you do not have an 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 away (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 RRF vials

- Store all vials of GONAL-F® RRF powder away from light.
- Store the powder 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.
- **Keep the GONAL-F RRF vials and all medicines out of the reach of children.**

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EMD Serono, Inc. is an affiliate of Merck: KGaA, Darmstadt, Germany

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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