

# 3 Steps to Reconstituting Gonal-f® RFF 75 IU Vial



## Gonal-f® RFF (follitropin alfa for injection) 75 IU Vial

Gonal-f® RFF 75 IU Vial —



Prefilled Syringe of Sterile Water for Injection, USP (1 mL)

18 G 1½" Mixing Needle —



— 29 G ½" Injection Needle

### 1 Mixing (reconstituting)



Wash hands with soap and water.

Flip off the protective plastic cap of the Gonal-f® RFF (follitropin alfa for injection) vial and wipe vial top with an alcohol swab.

Hold the barrel of the prefilled syringe of Sterile Water in one hand. Carefully twist off the protective cap of the prefilled syringe.

Remove the safety seal cover of the 18 G 1½" 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 the needle or allow it to touch any surface.

Place the vial of Gonal-f® RFF powder on a flat surface. Position the needle in a straight, upright position over the marked center circle of the rubber stopper on the vial.

Insert the needle of the prefilled syringe straight down through center circle.

Slowly inject the water by depressing the syringe plunger. Gently rotate the vial between your fingers until the powder is dissolved. **DO NOT** shake.

Invert the vial and pull back the 18 G 1½" 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 1½" mixing needle from the syringe and immediately dispose of the needle in your safety container. Do not use this needle for injection.

*Note: If your dose requires more than 1 vial of Gonal-f® RFF 75 IU, use the same 18 G 1½" needle and syringe now containing the mixture to reconstitute additional vials.*

### 2 Preparing the dose



**Determining your dose:** Your doctor will prescribe you a specific dose of Gonal-f® RFF (follitropin alfa for injection). A healthcare professional should show you how to locate the syringe marking that corresponds to your dose.

Check that the Gonal-f® RFF (follitropin alfa for injection) liquid solution is clear. Do not use if it contains any particles. If this happens, report this to your doctor, nurse, or pharmacist immediately.

Allow the liquid solution to adjust to room temperature prior to administering your injection.

Remove the safety seal cover from the 29 G 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 the needle or allow it 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 administration syringe is now filled with the prescribed dose of Gonal-f® RFF and is ready for administration.

Use reconstituted Gonal-f® RFF 75 IU vial immediately.

### 3 Injecting the dose



Change the injection site each day to minimize discomfort. Usual injection sites include the skin on the stomach, upper arm, or upper leg.

Uncap the syringe and inject the prescribed dose as directed by your doctor.

Dispose of all used syringes and needles safely in the container.

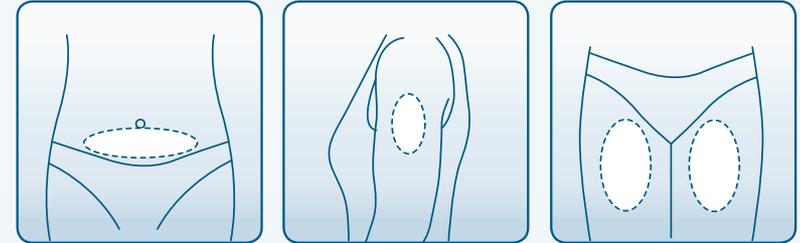
**IMPORTANT:**

The Gonal-f<sup>®</sup> RFF (follitropin alfa for injection) powder vials may be stored refrigerated or at room temperature (36° F to 77° F). Protect from light. Use immediately after reconstitution. Discard unused material.

The injection syringes provided with Gonal-f<sup>®</sup> RFF 75 IU are designed for use only with this product. Do NOT use the injection syringes to administer other drugs or hormones. All unused syringes should be discarded.

Your doctor, nurse, or pharmacist should show you how to set the prescribed dose and use the syringe.

**For Gonal-f<sup>®</sup> RFF (follitropin alfa for injection), usual injection sites include: the stomach, upper arm, and upper leg.**



**Get ready to learn more about Gonal-f<sup>®</sup> (follitropin alfa for injection)**

Visit [FertilityLifeLines.com](http://FertilityLifeLines.com) for a range of medication support material, including how-to videos on dosing and administration for the Gonal-f<sup>®</sup> products.



**Toll Free 1-866-LETS TRY (1-866-538-7879)**  
[www.fertilitylifelines.com](http://www.fertilitylifelines.com)

**Indication:**

Gonal-f<sup>®</sup> RFF (follitropin alfa for injection) is indicated for (1) the induction of ovulation and pregnancy in the anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure and (2) for the development of multiple follicles in the ovulatory patient participating in an ART program.

Gonal-f<sup>®</sup> RFF contains follitropin alfa, which is similar to the human hormone follicle-stimulating hormone, referred to as FSH. FSH belongs to a group of human reproductive hormones.

Gonal-f<sup>®</sup> RFF should be prescribed only by doctors specializing in infertility problems and their treatment.

**Important Risk Information:**

Gonal-f<sup>®</sup> RFF should not be used in patients with allergies to recombinant human FSH products or any other ingredients in the medication.

Patients with a history of cancer of the sex organs or brain, uncontrolled thyroid or adrenal disease should not use Gonal-f<sup>®</sup> RFF. Women with a history of abnormal bleeding from the uterus or vagina or with swollen, enlarged, or painful ovaries should speak to their doctor before starting treatment.

RFF, Revised Formulation Female

The lowest dose expected to achieve the desired results should be used. A doctor should monitor a woman's response often to avoid overdose, which can lead to serious side effects, including blood clots.

Women should contact their doctor if severe pain or bloating in the stomach or pelvic area, severe upset stomach, vomiting, and weight gain are experienced during treatment. These could be signs of a rare but serious condition known as Ovarian Hyperstimulation Syndrome, or OHSS, which can result in hospitalization.

Use of Gonal-f<sup>®</sup> RFF by a woman can be associated with fertilization of more than 1 egg. This can lead to complications for the woman and the birth of 2 or more babies.

The most common side effects reported were headache, ovarian cysts, upset stomach, and sinus infection. Injections may cause some discomfort.

**For more information, patients should refer to the enclosed prescribing information and patient information leaflet and talk to their doctor.**