

GONAL-f® RFF 75 IU,  
GONAL-f® Multi-Dose 450 IU, 1050 IU  
GONAL-f® RFF Pen 300 IU, 450 IU, 900 IU



**Description:** Gonal-f® is a FSH preparation made by recombinant DNA technology. Gonal-f® is packaged in monodose vials of 75 IU (International Units) and Multi-Dose vials containing 450 IU and 1050 IU. Each vial of Gonal-f® contains powdered medication with prefilled syringes of diluent. Gonal-f® Multi-Dose vials use specifically marked syringes to draw up the correct dose of medication, and inject subcutaneously. The Gonal-f® RFF Pen is a disposable, premixed, prefilled pen-like medication delivery system. Gonal-f® RFF Pen is available in 3 strengths - 300 IU, 450 IU and 900 IU.

**How it works:** Gonal-f® is a gonadotropin that stimulates the ovaries to produce eggs.

**Potential side effects:** Side effects may include some local discomfort, bruising and soreness at the injection site. Changes in mood, abdominal discomfort, bloating and cramping, ovarian cysts, breast pain, back pain, constipation and headache are other possible minor side effects. Multiple births occur in about 20-25% of pregnancies, of which 70% are twins. Excessive enlargement of the ovaries, called ovarian hyperstimulation (OHSS) may occur. Symptoms of OHSS include excessive fluid retention and severe abdominal discomfort.

**Storage:** Gonal-f 75 IU Vial - Store at room temperature or refrigerate (36-77°F) until expiration date. Do not freeze. Protect from light. After reconstitution/mixing: Use immediately. Discard unused material. Do not store drug in the syringe.

Gonal-f Multi-Dose 450 IU, 1050 IU - Before reconstitution/mixing: Store at room temperature or refrigerated (36-77°F) until expiration date. After reconstitution/mixing: Store at room temperature or refrigerated for up to 28 days. Do not store drug in syringe. Do not freeze. Protect from light.

*NOTE: Once reconstituted/mixed write the day of reconstitution/mixing on the box in order to keep track of its 28 day shelf life.*

Gonal-f Pens 300 IU, 450 IU, 900 IU - Before first use: Store refrigerated (36-46°F) until expiration date or at room temperature (68-77°F) for up to 3 months or until expiration, whichever occurs first. After initial use: Store at room temperature or refrigerated for up to 28 days. Protect from light. Do not freeze.

## GONAL-f® RFF 75 IU Vial

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- Mixing :
- Pop off the plastic top of powdered medication vial.
  - Swab the top of the vial with an alcohol pad to prevent contamination.
  - Hold the barrel of the prefilled syringe of diluent in one hand. Firmly hold the plastic cap between the thumb and forefinger of the other hand and with a downward motion, gently snap and pull off the cap. If the gray cap remains, simply remove it.
  - Attach the 18 gauge 1 ½" needle to syringe by twisting until tightened and remove needle cap.
  - Inject all of the contents of the prefilled diluent syringe into the vial of powdered medication.
  - Invert the syringe as one complete unit. Make sure the tip of the needle is **BELOW** the liquid level and pull the plunger to withdraw the entire contents of the vial.  
*NOTE: Withdraw liquid slowly and cautiously to prevent plunger from separating from syringe.*
  - If you are mixing a single vial, you are now ready for your injection. Withdraw the needle from the vial and carefully recap and replace the mixing needle with the smaller subcutaneous injection needle (usually a ½" needle) and prepare for your injection.
  - Invert the syringe so the needle is pointing upwards and tap the syringe to force any air bubbles to the top. Depress the plunger to expel the air.  
*PLEASE REFER TO PAGE 12 FOR SUBCUTANEOUS INJECTION INSTRUCTIONS*

## Mixing More than One Vial of GONAL-f® RFF 75 IU

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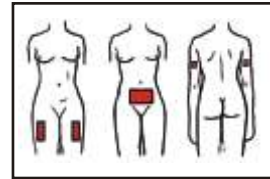
- Inject the contents of the syringe (powdered medication mixed with diluent) directly into the next vial of powdered medication, slowly and cautiously. **(Do not use more diluent for additional vials of Gonal-f® RFF 75 IU). This will increase the dosage without increasing the liquid volume.** Rotate the vial between your thumb and index finger until the solution is clear.
- Withdraw the newly mixed Gonal-f® RFF 75 IU from the second vial back into the syringe.
- Invert the syringe so the needle is pointing upwards and tap the syringe to force any air bubbles to the top. Depress the plunger to expel the air. Repeat until you have reached your prescribed vial dosage. Withdraw the medication mixture from the final vial into the syringe and prepare for your injection.  
When you are ready for your injection, recap and remove the mixing needle and replace it with a smaller subcutaneous injection needle (usually ½" needle).  
*PLEASE REFER TO PAGE 12 FOR SUBCUTANEOUS INJECTION INSTRUCTIONS*

## GONAL-f® Multi-Dose 450 IU, 1050 IU

- Mixing :
- Pop off the top of powdered medication of Gonal-f® Multi-Dose.
  - Swab the top of the vial with an alcohol pad to prevent contamination.
  - Remove the cap from the needle and inject all of the contents of the prefilled diluent syringe into the vial of powdered medication. **DO NOT SHAKE VIAL.**
  - After injecting the diluent into the Multi-Dose vial of Gonal-f, dispose of the syringe into the Sharps waste container. It is unnecessary to recap the needle as this could cause injury. **DO NOT USE THIS SYRINGE TO INJECT YOUR DOSE.** Use the specifically marked syringes packaged with the medication.
  - Swab the top of the vial with an alcohol pad to prevent contamination.
  - Firmly insert the needle through the rubber stopper into the vial. Invert, or turn upside down, the syringe as one complete unit. Make sure the tip of the needle is **BELOW** the liquid level and pull the plunger to withdraw the prescribed dose.
  - Withdraw the needle and prepare for your subcutaneous injection.  
*PLEASE REFER BELOW FOR SUBCUTANEOUS INJECTION INSTRUCTIONS*

### Subcutaneous Injection Instructions

- Cleanse your selected SUBCUTANEOUS injection site with an alcohol wipe and allow to dry.
- While holding the syringe with your dominant hand between your thumb and finger (as you would a pencil), pinch the skin (with your other hand) at the site you have selected.
- With a quick, dart-like motion, insert the entire needle (up to the hub of the syringe) at a 90° or a 45° angle and depress the plunger slowly and carefully.
- After the injection is complete, quickly pull out the needle. If bleeding, apply pressure to the injection site with a sterile gauze pad. If stinging occurs after your injection, you may gently massage the injection site to alleviate your discomfort.
- Use Sharps waste container for needle and syringe.



With Gonal-f RFF 75 IU

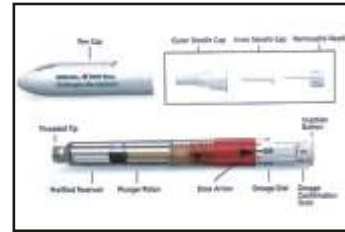


With Gonal-f  
Multi-Dose 450 IU



With Gonal-f  
Multi-Dose 1050 IU

## GONAL-f® RFF Pen Instructions



### Priming of Pen *(Prior to initial use of each pen)*

- Remove pen cap and wipe threaded tip with an alcohol wipe.
- Remove peel tab from outer needle cap and press threaded tip of pen into outer needle cap. Twist pen clockwise until needle is tightened. Pull off and **SAVE** outer needle cap.
- Turn dosage dial to 37.5 IU. Pull out injection button as far as it will go.
- Remove inner needle cap, point needle upwards and tap pen to force any air bubbles to top and push in injection button completely.
- Hold until a click is heard. A small amount of liquid should appear from needle tip. If no liquid appears, begin priming procedures again.

### Injection Instructions

- Remove pen cap and wipe threaded tip with an alcohol wipe.
- Remove peel tab from outer needle cap and press threaded tip of pen into outer needle cap. Twist pen clockwise until needle is tightened. Pull off and **SAVE** outer needle cap.
- Turn dosage dial to prescribed dose. Make sure that correct dose is lined up with black arrow. Dial can be turned in either direction.
- Load the dose by pulling out injection button as far as it will go. Confirm correct dose by looking at red dosage confirmation scale. The last visible flat red arrow indicates the loaded dose.



*(NOTE: If loaded dose is lower than set dose, there is not enough medication to complete dose. Use new Gonal-f® RFF Pen to complete dose.)*

- Cleanse your selected subcutaneous injection site with an alcohol wipe and allow to dry.
- Remove outer and inner needle cap and inject needle into skin at a 90° angle and push injection button until it stops clicking. After last click, release pressure on button and count to **five** before removing needle from site.
- Replace outer needle cap onto needle, grip outer needle cap firmly and unscrew pen from needle by turning pen counter-clockwise. Dispose of needle in Sharps container.
- Dispose of pen when empty.