

**GONAL-f® RFF 75 IU,
GONAL-f® Multi-Dose 450 IU, 1050 IU,
GONAL-f® RFF Redi-ject™ 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 Redi-ject 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 hyper-stimulation (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 Redi-ject 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

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.

PROCEED TO SUBCUTANEOUS INJECTION INSTRUCTIONS

MIXING MORE THAN ONE VIAL OF GONAL-f® RFF 75 IU VIAL

- 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).

PROCEED TO SUBCUTANEOUS INJECTION INSTRUCTIONS

GONAL-f® MULTI-DOSE 450 IU, 1050 IU

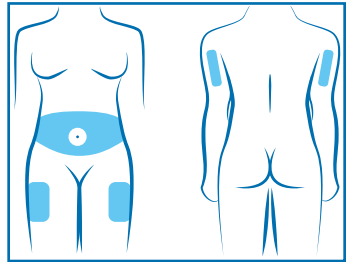
Mixing: • Pop off the top of powdered medication of Gonal-f Multi-Dose.

- 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.

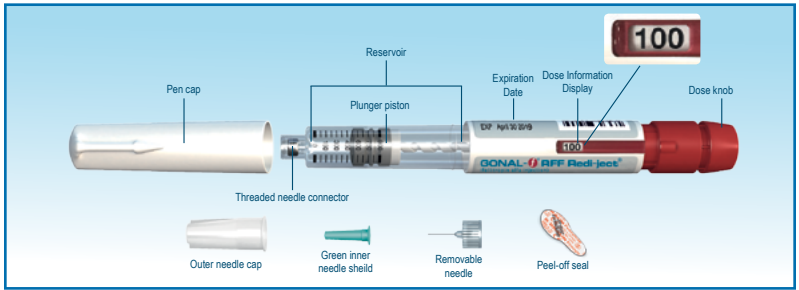
PLEASE REFER BELOW FOR SUBCUTANEOUS INJECTION INSTRUCTIONS

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.



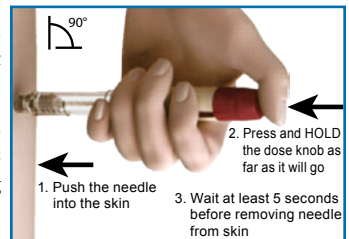
GONAL-f® RFF REDI-JECT™ PEN



INJECTION INSTRUCTIONS

Please use these instructions in conjunction with the manufacturer's directions

- 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.
- Hold pen with needle pointing towards ceiling. Tap pen and observe clear medication reservoir for any large air bubbles. A large air bubble is defined as one that covers the entire surface of the top of the reservoir. (This is a rare occurrence.)
- If a large air bubble is seen, turn the dose knob until the dose display reads “.25”.
- Remove and discard blue inner needle shield.
- Hold pen with needle pointing up and away from you, slowly press dose knob as far as it will go and release. A drop will appear at tip of needle.
- For pen usage, now turn dose knob to prescribed dose. Make sure that the correct dose is observed in the dose display.
- Cleanse your selected subcutaneous injection site with an alcohol wipe and allow to dry.
- While holding the pen with your dominant hand between your thumb and finger (as you would a pen), pinch the skin, if desired at the site you have selected.
- With a quick, dark-like motion, insert the entire needle into the skin at 90° angle. Press down on the knob as far as it will go and hold to the count of five before pulling the needle out of the skin.
- Carefully replace the outer needle cap onto the needle and push against a hard surface until a click is heard, ensuring the cap is on securely. Unscrew the covered needle from the pen by turning counter-clockwise. Dispose of needle in Sharps container.
- Check the dose display - it should read “0” indicating that the entire dose was received.
- If any number appears in dose display, document that amount. This indicates that there was not enough medication in the pen to deliver the entire dose, and the amount shown is the dosage needed, using a new Gonalf RFF Redi-ject pen to complete the dose. Repeat pen usage instructions with a new pen for dose completion.
- Dispose of pen when empty.



The Gonalf Redi-ject Pen may be OVERFILLED.