Read these instructions completely before you start treatment with Gonal-f RFF Redi-ject. Consult your healthcare provider with any questions.

Gonal-f RFF Redi-ject (follitropin alfa injection) is for use (subcutaneous).

Only use Gonal-f RFF Redi-ject if your healthcare provider trains you on how to use it correctly.

Keep the pen out of reach of children.

If you use medicine left in a pen after injecting, store it in the refrigerator or at room temperature for up to 28 days. After 28 days, you must throw away your pen in a FDA-cleared sharps disposal container. See Appendix C for proper disposal information.

For more information, call 1-866-534-7679.
To view the Instructions for Use video, please visit www.Rediject.com.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised: November 2017

Important

• The pen comes in 3 different IU amounts
  - 300 IU
  - 450 IU
  - 900 IU

Use the attached treatment diary to record your treatment. Refer to the treatment diary for sample entries.

Gather your supplies and set them aside:

- A flat, well-lit area
- A carton or package for your needles and pen
- The spirit or alcohol pads, and a writing utensil (not included)
- A treatment diary

Follow these easy instructions to complete your intended dose.

1. Put on your gloves.
2. Remove the pen from the carton.
3. Hold the pen with the tip of the needle pointing up. Silently press the dose knob in all the way. One or more tiny drops of liquid will appear at the tip of the needle. Release the dose knob. Make sure that the Dose Information Display reads “0”.
4. Go to Step 4 Dial your dose.

Appendix D: How to store your pen

Store all pens with the cap attached and away from light.

Store new pens 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) for up to 3 months or until the expiration date, whichever comes first.

Do not freeze the pen.

Do not throw the pen.

Keep the pen out of reach of children.

Do not throw away (dispose of) your used sharps disposal container. See Appendix C for proper disposal information.

Appendix C: How to throw away used needles and empty pens

Put used needles and empty pens in a 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 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
- Can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,
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Step 2 Get ready
- Wash your hands with soap and water and dry them well.
- Never shake the pen. If you shake the pen, air bubbles may appear in the medicine.
- Remove the pen and a new needle from the carton.

Step 3 Attach your needle
- Pull off the pen cap.
- Make sure the plastic reservoir that holds the medicine is not cracked. Confirm the medicine is clear, colorless, and does not contain particles. If the plastic is cracked or if the liquid is discolored or cloudy, get a new pen from your healthcare provider or pharmacist.
- Check that the needle’s peel-off seal is not broken. If it is, get a new needle.
- Peel off the needle cap.
- Push the needle on the clear, plastic end of the pen, and twist the needle until you cannot twist it anymore.
- Caution: Do not attach the needle too tightly, the needle could be difficult to remove after the injection.
- Pull off the outer needle cap and save it for removing the needle after the injection.
- Keep the needle pointing up, carefully pull off the green inner needle shield and throw it away.
- Warning: Do not recap the needle with the green inner needle shield, you could get a needle stick injury.

Step 4 Dial your dose
- Check for a droplet of liquid at the tip of the needle.
- Note: Call your healthcare provider if you are unsure of today’s intended dose.
- Caution: Do not push or pull the dose knob while you turn it to avoid damaging it.
- Turn the dose knob until your intended dose shows in the Dose Information Display.
- Note: You can turn the dose knob backward if you turn it past your intended dose.

Step 5 Inject your dose
- Important
- Make sure the Dose Information Display matches the intended dose recorded in Column 5 in your treatment diary.
- Example: If your intended dose is 300 IU, confirm that the Dose Information Display reads "300 IU".
- Caution: You might bend the needle if you do not insert the needle straight at a 90˚ angle.
- Hold the pen with the needle attached in one hand, and slip the needle into the outer needle cap without using your other hand.
- Push the capped needle against a firm, vertical surface, such as a green needle guard.
- Redi-ject carton or a wall, until you hear a “click.”
- Twist off the capped needle and throw it away in a FDA-cleared sharps disposal container. See Appendix C for proper disposal information.

Step 6 Remove and throw away your needle
- Warning: If the Dose Information Display does not show "0", you did not complete your dose.
- Fill in Column 7 of the treatment diary with the number in the Dose Information Display.
- You will need to use a second pen to inject the number shown in the Dose Information Display to complete your dose.

Step 7 Record your injection
- Important
- After injecting, fill in Column 7 in the treatment diary by recording the number you see in the Dose Information Display.
- If the Dose Information Display shows "0", you have completed your dose.
- If the Dose Information Display does not show "0", you did not complete your dose. You need to inject the number shown in the Dose Information Display using a second pen.
- Follow the instructions in Appendix A: Completing an incomplete dose.

Appendix A: Completing an incomplete dose
- The amount you need to inject using the second pen might be less than expected because of the extra medicine you received. Always inject the amount you wrote in Column 7 of the treatment diary to complete your dose.
- Refer to the treatment diary for sample entries.
- Note: The pen contains extra medicine to ensure that you receive the full amount indicated on the pen (300 IU, 450 IU, or 900 IU).

Appendix B: How to create a droplet of liquid
- If you do not see a droplet of liquid on the tip of the needle when using a pen for the first time, turn the dose knob until the Dose Information Display reads "0."
- With the needle pointing up, gently tap the reservoir so that any air bubbles rise to the top.

Appendix C: Proper disposal
- Proper disposal information.

Additional information
- The number recorded in Column 7 in the treatment diary indicates the number you need to dial with the second pen to complete today’s intended dose. To complete the dose with a second pen, repeat Steps 1 through 7.

APPENDIX A: HOW TO CREATE A DROPLET OF LIQUID

APPENDIX B: HOW TO CREATE A DROPLET OF LIQUID

APPENDIX C: PROPER DISPOSAL

Step 2 Choose and prepare your injection site
- Note: Your healthcare provider should show you the injection sites to use around your stomach area.
- Select your injection site and wipe the skin with an alcohol pad to clean the site.
- Choose a different injection site each time you give your injection to reduce redness, irritation or other skin problems.