GONAL-f® RFF Redi-ject®
(follitropin alfa injection)

Important

- **Read these instructions completely before you begin.**
- Gonal-f RFF Redi-ject (follitropin alfa injection) is for use **under the skin only** (subcutaneous).
- Only use Gonal-f RFF Redi-ject if your healthcare provider trains you on how to use it correctly.

Warning: Do not reuse needles.

Warning: Do not share the pen and needles with another person, because doing so can cause an infection.

- The pen comes in **3 different IU** amounts

300 IU/0.5 mL | 450 IU/0.75 mL | 900 IU/1.5 mL

- **Use the attached treatment diary to make sure you take the correct dose.** Consult your healthcare provider on proper use of your treatment diary.
- You might need to use more than one pen to give today's intended dose. Contact your healthcare provider with any questions.
- The Dose Information Display is used for setting your dose, to confirm a completed dose, and to display the amount remaining to complete your intended dose.

Gather your supplies

☐ Take the carton out of the refrigerator at least 30 minutes before you inject to let it warm to room temperature.



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

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

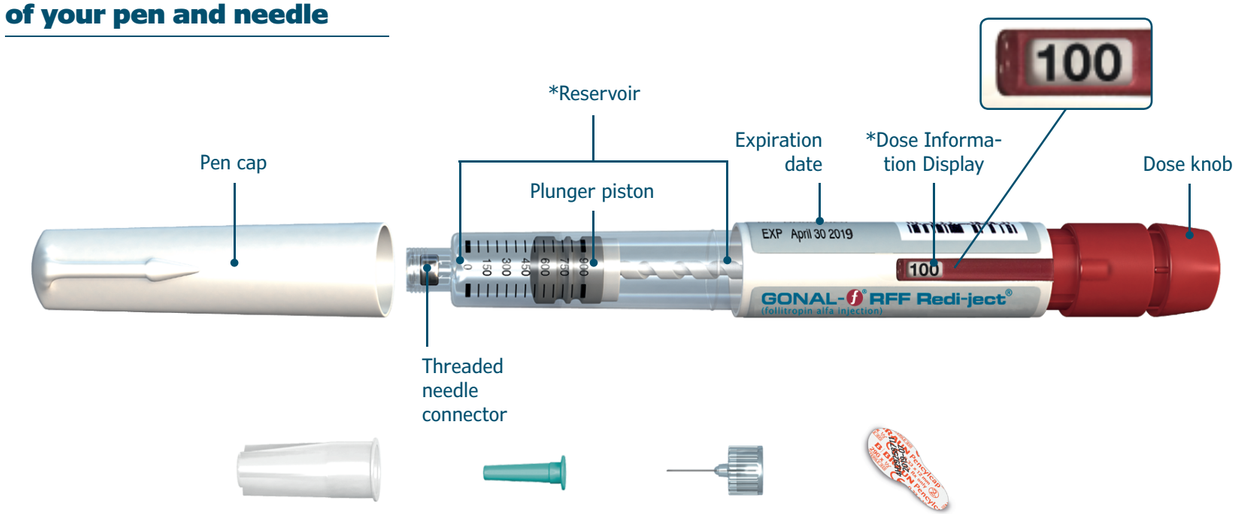
☐ Identify a firm, vertical surface, such as the side of your Gonal-f RFF Redi-ject carton or a wall.

☐ Fill in the first 5 columns of the treatment diary. Refer to the treatment diary for sample entries.

☐ You will also need a sharps container, alcohol pads, and a writing utensil (not included).



Get familiar with the parts of your pen and needle



*The numbers on the Dose Information Display and reservoir represent the number of International Units (IU) of medicine.

Please open to continue to Steps 1 through 7.

Cut or tear along dotted line.

Treatment Diary

Treatment day	Date	Time	Pen IUs	Intended Dose	After injecting, Dose Information Display shows "0" Yes/No	If column 6 is No, you did not complete your dose. Record the number shown in the Dose Information Display and inject the number shown using a second pen	Notes
1	2/14	6:30pm	300 IU 450 IU 900 IU	300	Yes	0	Dose Information Display shows "0"; you completed your injection.
2	2/15	6:30pm	300 IU 450 IU 900 IU	300	No	100	Incomplete injection; get second pen
2	2/15	6:35pm	300 IU 450 IU 900 IU	100	Yes	0	Dose Information Display shows "0"; you completed your injection.
			1 2 3 4 5 6 7 8				

Treatment Diary

Treatment day	Date	Time	Pen IUs	Intended Dose	After injecting, Dose Information Display shows "0" Yes/No	If column 6 is No, you did not complete your dose. Record the number shown in the Dose Information Display and inject the number shown using a second pen	Notes
			1 2 3 4 5 6 7 8				

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.

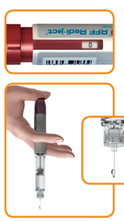
☐ If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- 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
- 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** 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.



☐ Hold the pen with the needle pointing up. Slowly 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".

☐ 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.

☐ Keep the pen out of reach of children.

☐ If you have 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 1-866-538-7879.
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

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

©2017 EMD Serono, Inc.

EMD Serono, Inc.
Rockland, MA 02370

N19Z01050



300 IU/0.5 mL
450 IU/0.75 mL
900 IU/1.5 mL

For subcutaneous injections
Rx only

GONAL-f® RFF Redi-ject®
(follitropin alfa injection)

INSTRUCTIONS FOR USE

Step 1 Get ready

- ☐ Wash your hands with soap and water and dry them well.



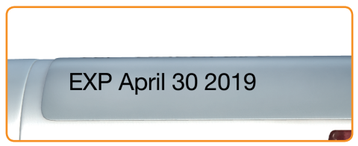
Caution: Do not shake the pen. If you shake the pen, air bubbles may appear in the medicine.

- ☐ Remove the pen and a new needle from the carton.



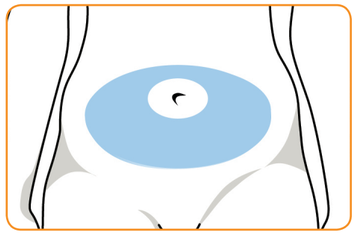
- ☐ Check the expiration date on the pen label.

Warning: Do not use an expired pen. Get a new pen from your healthcare provider or pharmacist.



Step 2 Choose and prepare your injection site

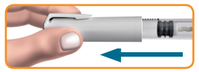
Note: Your healthcare provider should show you the injection sites to use around your stomach area.



- ☐ 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.

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 seal.

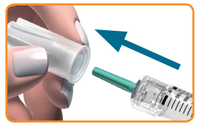


- ☐ Push the needle on the clear, plastic end of the pen, and twist the needle until you cannot twist it anymore.



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.



- ☐ **Keeping 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.

Important

If	Then
Using a new pen 	Check for a droplet of liquid at the tip of the needle. • If you see a droplet go to Step 4 Dial your Dose. • If no droplet is seen, or you are unsure, follow the instructions in **Appendix B**.
Re-using a pen	You do not have to check for droplets of liquid at the tip of the needle. Go to Step 4 Dial your Dose.

Step 4 Dial your dose

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.

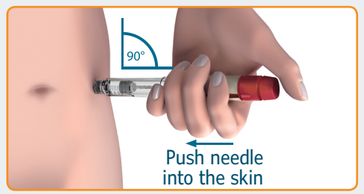
Step 5 Inject your dose

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 150 IU, confirm that the Dose Information Display reads 150.





Caution: You might bend the needle if you do not insert the needle straight in at a 90° angle.

- ☐ Hold the pen at a 90° angle to the injection site, and push the needle into your skin.
- ☐ Use your thumb to press the dose knob straight down as far as it will go.

Caution: Do not release the dose knob until you remove the needle from your skin. Hold the dose knob down for a slow count of 5 before you remove the needle from your skin. Then release the knob after removal of the needle from your skin.



- ☐ Remove the needle from your skin, release the dose knob, and put the pen on the table.
- ☐ After injecting, fill in "Yes" or "No" in Column 6 of the treatment diary, to record if the Dose Information Display shows "0".

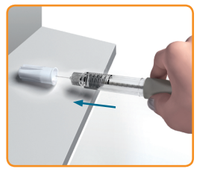
Warning: If the Dose Information Display does not show "0", you did not complete your dose.

- 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 6 Remove and throw away your needle

Warning: You must remove the needle from the pen and throw away after each injection to avoid risk of infection.

- ☐ Lay the outer needle cap on its side on a flat surface.
- ☐ Hold the pen with the needle attached in one hand, and slip the needle into the outer needle cap without using your other hand.



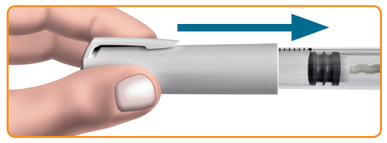
- ☐ Push the capped needle against a firm, vertical surface, such as a Gonal-f RFF Redi-ject carton or a wall, until you hear a "click".



- ☐ Twist off the capped needle and throw it away in a FDA-cleared sharps disposal container. See **Appendix C** for proper disposal information.



- ☐ After removing the needle, recap the pen.



- ☐ If the pen is empty after your injection, throw it away in a FDA-cleared sharps disposal container. See **Appendix C** for proper disposal information.

Step 7 Record your injection

Important

- ☐ After injecting, fill in Column 7 of 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.
  - The amount you need to inject using the second pen might be less than expected because of the extra medicine (see note below). **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.

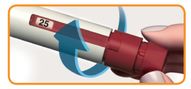
Note: The pen contains extra medicine to ensure that you receive the full amount indicated on the pen (300 IU, 450 IU, or 900 IU).

Appendix A: Completing an incomplete dose

- ☐ 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 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 "25".



- ☐ With the needle pointing up, gently tap the reservoir so that any air bubbles rise to the top.



Cut or tear along dotted line.

Treatment Diary

Treatment day	Date	Time	Pen IUs (300 IU / 450 IU / 900 IU)	Intended Dose	After injecting, Dose Information Display shows "0" Yes/No	If column 6 is No, you did not complete your dose. Record the number shown in the Dose Information Display and inject the number shown using a second pen	Notes
1	2	3	4	5	6	7	8

Treatment Diary

Treatment day	Date	Time	Pen IUs (300 IU / 450 IU / 900 IU)	Intended Dose	After injecting, Dose Information Display shows "0" Yes/No	If column 6 is No, you did not complete your dose. Record the number shown in the Dose Information Display and inject the number shown using a second pen	Notes
1	2	3	4	5	6	7	8