

**Gonal-f® RFF Pen**  
**(follitropin alfa injection)**

\*revised formulation female

**Patient's Information Leaflet**

Read the patient information before you start using the Gonal-f® RFF Pen. Read the patient information each time you get a refill, because there may be new information. This leaflet does not take the place of talking with your healthcare provider about your condition or treatment.

**What is the Gonal-f® RFF Pen?**

The Gonal-f® RFF Pen is a prescription injectable medicine provided in a device that contains the hormone follicle stimulating hormone (FSH). FSH helps healthy ovaries to make eggs in women.

**What are the uses of the Gonal-f® RFF Pen?**

Doctors specializing in infertility or reproductive health prescribe the Gonal-f® RFF Pen to those patients needing medical assistance to have a child. After a thorough medical exam to determine your specific medical condition, your doctor may prescribe the Gonal-f® RFF Pen because you need help with producing eggs or you need supplementation as part of your treatment program. The Gonal-f® RFF Pen is used only for women seeking pregnancy. The Gonal-f® RFF Pen may be one of several drugs prescribed to you as part of your treatment program.

Gonal-f® RFF Pen is used:

- in certain infertile women to help with ovulation (production and release of a mature egg) and pregnancy. Gonal-f® RFF Pen will not help women whose ovaries no longer work because of a condition called primary ovarian failure.
- in women who are in an Assisted Reproductive Technology (ART) program, such as *in vitro* fertilization, to help their ovaries make more eggs.

**Who should not use Gonal-f® RFF Pen?**

Do not use the Gonal-f® RFF Pen if you:

- are allergic to recombinant human FSH products (see the end of this leaflet for a list of all the ingredients in the Gonal-f® RFF Pen)
- have primary ovarian failure (your ovaries no longer make eggs)
- are pregnant or think you may be pregnant
- have uncontrolled thyroid or adrenal problems
- have cancer in your female organs (ovaries, breast, uterus)
- have a pituitary tumor or other tumor in your brain
- have abnormal bleeding from your uterus or vagina

- have ovarian cysts or enlarged ovaries, not due to polycystic ovary syndrome (PCOS)

### **Tell your healthcare provider if you are breastfeeding**

It is not known if Gonal-f® RFF Pen passes into your milk.

### **Can you use the Gonal-f® RFF Pen with other medicines?**

Inform your doctor and pharmacist if you are taking or have taken any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements. It is not known if Gonal-f® RFF Pen and other medicines can affect each other.

### **Storing the Gonal-f® RFF Pen Before the First Use**

Store the Gonal-f® RFF Pen refrigerated (2°-8°C/36°-46°F) until dispensed. Upon dispensing, the pen may be stored by the patient refrigerated (2°-8°C/36°-46°F) until the expiration date, or at room temperature (20°-25°C/68°-77°F) for up to **three months** or until the expiration date, whichever occurs first. Protect from light. Do not freeze.

### **How should I use Gonal-f® RFF Pen?**

- Use Gonal-f® RFF Pen exactly as prescribed. Your doctor will prescribe the dose that is right for you and your condition. Do not change the dose of Gonal-f® RFF Pen unless your doctor tells you to. Your doctor or healthcare provider will tell you the number of units (IU FSH) of Gonal-f® RFF Pen to use each day and the number of days to use the same Pen.
- Gonal-f® RFF Pen is given by an injection just under the skin (subcutaneous injection). Your doctor's office will teach you how to inject yourself. See the end of this leaflet for detailed instructions, "How do I prepare and use the Gonal-f® RFF Pen?" Do not inject Gonal-f® RFF Pen at home until your healthcare provider has taught you the correct way.
- Your condition must be closely monitored by your healthcare provider while you are using Gonal-f® RFF Pen. Your doctor may do regular ultrasound tests and blood tests to make sure that Gonal-f® RFF Pen is not making your ovaries too active (hyperstimulation) which can lead to rare, but serious side effects. Your doctor will decide if it is safe for you to continue with your fertility treatments based on the results of these tests.
- If you use too much Gonal-f® RFF Pen, call your doctor right away.
- Do not use Gonal-f® RFF Pen for a condition for which it was not prescribed. Do not give Gonal-f® RFF Pen to other people, even if they have the same symptoms you have.

### **What are the possible side effects of the Gonal-f® RFF Pen?**

The most common side effects with the Gonal-f® RFF Pen are headache, stomach pain, stomach bloating, nausea, and ovarian hyperstimulation syndrome. Bruising, pain, and redness can happen at the injection site.

Gonal-f® RFF Pen and other FSH products can cause serious side effects including:

- **Ovarian Hyperstimulation Syndrome (OHSS).** OHSS causes fluid to suddenly build up in the stomach area, chest area, and heart area. Stop using Gonal-f® RFF Pen and call your doctor right away if you get severe lower stomach area (pelvic) pain, nausea, vomiting, or weight gain.
- **Lung and blood vessel problems.** FSH products may cause serious lung problems including fluid in the lungs, trouble breathing, and worsening of asthma. Blood vessel problems include blood clots and strokes.
- **Multiple births.** FSH products can cause multiple births. Your healthcare provider will discuss your chances of multiple births.

These are not all the side effects of Gonal-f® RFF Pen. As with any medication, report any and all side effects, symptoms, or physical changes to your healthcare provider.

**What should you do if you forget to take your dose?**

Do NOT double the dose of Gonal-f® RFF Pen prescribed. Contact your doctor if you forget to take a dose of Gonal-f® RFF Pen.

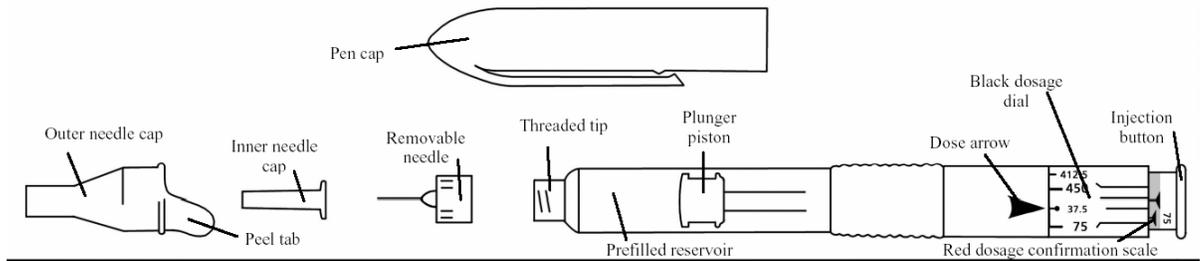
**REVIEW THESE STEPS BEFORE YOU PREPARE OR ADMINISTER GONAL-F® RFF PEN**

**How do I prepare and use the Gonal-f® RFF Pen?**

**Getting ready**

*Make sure you have all the supplies listed below before you begin.*

1. Gonal-f® RFF Pen
  - Make sure the Gonal-f® RFF Pen is at room temperature before using.
  - Make sure the liquid in the Pen is clear. Do not use the Gonal-f® RFF Pen if it contains any particles. Get a replacement from your doctor, nurse or pharmacist.



2. One new single-use, disposable administration needle supplied with the Gonal-f® RFF Pen.
3. Alcohol wipes and gauze pad.

4. Safety container (hard plastic or metal container) to use for safe disposal of used needles.

Before you start, wash your hands with soap and water. On a clean surface, layout everything you need.

### **Preparing the Pen**

**Note:** Read steps 1 through 7 prior to pulling the injection button on the pen.

**Do not pull the injection button until the dose is dialed and you are ready for injection.**

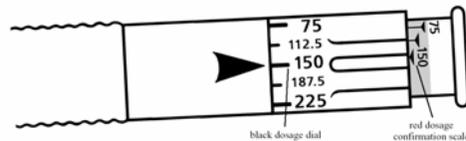
1. Remove the protective pen cap. **Clean the threaded tip of pen with an alcohol swab.**
2. Take a single-use disposable needle provided in the Gonal-f® RFF Pen carton. If the peel tab of the needle is damaged or loose, do not use it. Discard the needle and take a new one. Remove the peel tab from the outer needle cap.
3. With the tab removed, hold the outer needle cap firmly in one hand and hold the pen firmly in the other hand. Press the threaded tip of the Gonal-f® RFF Pen into the open end of the needle cap and twist it clockwise until it is securely fixed.
4. Once the needle is securely attached, remove the outer needle cap by gently pulling it straight off. Do NOT remove the inner needle cap—leave it where it is. Do NOT throw away the outer needle cap—you will need it when you are ready to remove the needle following your injection.

**Note:** Use only the single-use disposable needles provided within the Gonal-f® RFF Pen carton or compatible needles distributed separately by EMD Serono, Inc.

**This step only needs to be performed before the first use of each new pen; Otherwise, proceed to Step 6.**

5. You must prime the pen before the first use. You only need to prime the first time you use a new pen. Do the following steps to get your pen ready for use:
  - Check to make sure the dose arrow is set at 37.5. If not, turn the dosage dial (black numbers) to align the dose arrow with 37.5.
  - Pull out the injection button as far as it will go.
  - Remove the inner needle cap and hold the pen with the needle pointing upwards.
  - Tap the drug reservoir gently with your finger so that any air bubbles rise up towards the needle. (If a few small air bubbles remain, do not worry; this is normal).
  - Keep the needle pointing upright and push in the injection button completely. Stop pushing after you hear the first click. A small amount of liquid should come out of the needle indicating that the pen is ready for use. The amount of liquid seen at the needle tip is part of the extra medicine from the pen. If no liquid appears the first time, repeat these steps until liquid comes out of the needle tip.
  - Replace the inner needle cap.

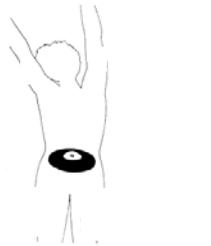
6. Select your prescribed dose by turning the dosage dial (black numbers) to the proper dose mark on the dial in front of the arrow mark. Carefully check the dosage dial before proceeding. Once you have set the dose correctly, load the pen by pulling out the injection button straight as far as it will go. **Do not twist the injection button while loading the pen.**
7. Check the red dosage confirmation scale on the injection button to ensure the correct dose has been loaded and that the accurate dose will be injected. The loaded dose is shown by the last mark (flat arrow) on the red dosage confirmation scale that is fully visible.



- If you accidentally pull out the injection button with an incorrect dose setting, do not inject. If the set dose is lower than the correct dose to be administered, you can turn the dosage dial to the correct dose and pull out the injection button again. If the set dose is higher than the dose to be administered, discard the dose by pushing all the liquid out into the safety container and repeat the previous steps for setting the dose.

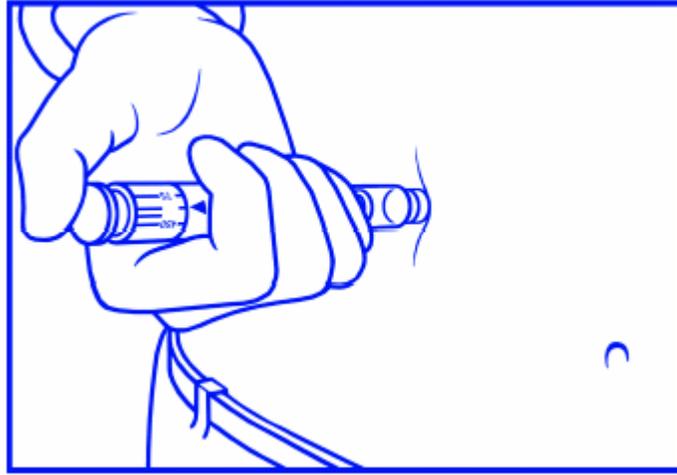
### **Injecting the dose**

Suitable injection sites on the stomach will be advised by your fertility specialist. Occasionally, your fertility specialist may suggest an alternative site.



8. Clean the injection site with an alcohol swab and allow it to air dry.
9. Remove the inner needle cap from the needle on the pen. Do not touch the needle or allow the needle to touch any surface.

10. To inject, insert the needle into the skin at a 90° angle and push the injection button—you will hear the button clicking. After the last click, **allow** the needle to remain in the skin for at least 5 seconds. This will ensure that you inject the full dose.



11. After the injection is complete, **keep the injection button pressed down and** remove the needle out of your skin. **Apply** pressure using a gauze pad.
12. Each time you finish an injection, remove and discard the used needle as follows. Hold the Gonal-f® RFF Pen firmly by the drug reservoir. Carefully replace the outer needle cap onto the needle. Gripping the outer needle cap firmly, remove the needle by unscrewing the pen counter-clockwise and dispose of the needle in your safety container.
13. Replace the pen cap and store properly. See the section “Storing the Gonal-f® RFF Pen Between Uses.”

**If there is not enough medicine remaining in the Gonal-f® RFF Pen.**

- After several doses, you may not have enough Gonal-f® RFF remaining in the pen to administer another full dose. The red dosage confirmation scale on the injection button enables you to check that the correct dose has been loaded. Dial your dose and pull out the injection button. It will go out only as far as the amount of drug that is left in the pen. The amount of drug left in the pen will be indicated by the last mark (flat arrow) on the red dosage confirmation scale that is fully visible. If this amount is lower than the set dose, the amount of Gonal-f® RFF Pen left in the pen is not enough to complete your full dose. If the loaded dose is not sufficient to complete your injection you have two options:
  - Inject the partial dose (what is left in the pen) and then immediately complete the dose with a new Gonal-f® RFF Pen, remembering to measure out only what is required to complete your daily dose.
  - Discard the Gonal-f® RFF Pen and inject the full dose using a new pen.

- It is common for a small amount of drug to be leftover in the Gonal-f® RFF Pen. This is normal. Any drug remaining in the Gonal-f® RFF Pen after your treatment is complete should be discarded.

### **Storing the Gonal-f® RFF Pen Between Uses**

- After each use, the Gonal-f® RFF Pen must be stored away from light and may be stored refrigerated or at room temperature between 36°– 77° F (2°- 25° C) for up to 28 days.
- Do not store above 77°F (25°C).
- If you are traveling, keep the Gonal-f® RFF Pen stored away from light and extreme temperatures. Do not freeze.
- Allow the liquid solution to adjust to room temperature prior to administering your injection.
- Check that the liquid is clear. Do not use if it contains any particles. Report this to your doctor, nurse or pharmacist immediately.
- Keep the Gonal-f® RFF Pen and all medicines out of the reach of children.

### **What are the ingredients in Gonal-f® RFF Pen?**

Active ingredient: follitropin alfa (r-hFSH)

Inactive ingredients: sucrose, meta-cresol, di-sodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate monohydrate, methionine, Poloxamer 188, O-phosphoric acid and/or sodium hydroxide

### **Where can more information about the Gonal-f® RFF Pen be obtained?**

This leaflet is a summary of the important patient information about the Gonal-f® RFF Pen. If you have any questions or problems, talk to your doctor or other health care provider. The Gonal-f® RFF Pen is manufactured and distributed by EMD Serono, Inc. You can also call 1-866-LETS TRY (1-866-538-7879) or log on to

[www.fertilitylifelines.com](http://www.fertilitylifelines.com).

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