

The GONAL-*f*[®] RFF Redi-ject[™] Teaching Guide (follitropin alfa injection)

300 IU/0.5 mL

450 IU/0.75 mL

900 IU/1.5 mL



IMPORTANT: Gonal-*f*[®] RFF Redi-ject[™] (follitropin alfa injection) is for use **under the skin only** (subcutaneous).

Do not share your pen and needles with another person, as this can cause an infection.

Gonal-*f*[®] RFF Redi-ject[™] comes in **3 different dosage strengths**, and all the pens look the same. Your healthcare provider (HCP) will prescribe the correct dose and pen for you and may change your dose during your treatment.

This guide is meant to be a supplement to the Instructions for Use

Step 1 PREP THE PEN

Take the pen out of the refrigerator at least 30 minutes before your injection so it can warm to room temperature.

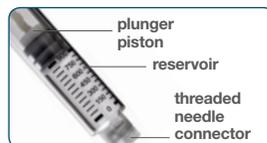
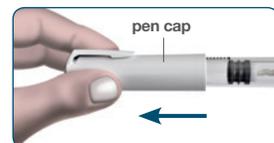
Prepare a clean, flat surface, such as a table or countertop, with a firm surface, like a wall, nearby.

Gather all the supplies: pen(s), needle(s), 1 or 2 alcohol and gauze pads, a sharps disposal container, and a treatment diary. Become familiar with the parts of your pen and needle. A description of these can be found in the *Instructions for Use*.

Wash your hands with soap and water. Dry your hands well.

Remove the pen and a new needle from the carton. Check the **expiration date** on the pen label.

Do not shake the pen. Shaking the pen may cause air bubbles to appear in the reservoir.



Pull off the **pen cap**. Save it for later. Check the reservoir for cracks. The liquid should be clear and colorless with no particles. Set the dose display to "0."

INDICATION

Gonal-*f*[®] RFF Redi-ject[™] is an injection Pen that delivers a prescription medicine containing follicle-stimulating hormone (FSH) used in infertile women to: help healthy ovaries develop (mature) and release an egg; and cause your ovaries to make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) program.

IMPORTANT RISK INFORMATION

Do not use the Gonal-*f*[®] RFF Redi-ject[™] if you:

Are allergic to recombinant human FSH or any of the ingredients listed here: follitropin alfa (r-hFSH), sucrose, meta-cresol, disodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate monohydrate, methionine, Poloxamer 188, O-phosphoric acid, sodium hydroxide; have ovaries that no longer make eggs (primary ovarian failure); are pregnant or think you may be pregnant; have uncontrolled thyroid or adrenal problems; have a

tumor in your female organs, including your ovaries, breast, or uterus; have a tumor in your brain, such as a tumor in your pituitary or hypothalamus; have abnormal bleeding from your uterus or vagina; and/or have ovarian cysts or large ovaries, not due to polycystic ovary syndrome (PCOS).

Before you use Gonal-*f*[®] RFF Redi-ject[™], tell your healthcare provider if you:

Have or have had asthma; have been told by a healthcare provider that you have an increased risk for blood clots (thrombosis); have ever had a blood clot (thrombosis), or anyone in your family has ever had a blood clot (thrombosis); have had abdominal surgery; have had twisting of your ovary (ovarian torsion); had or have a cyst on your ovary; have polycystic ovarian disease; have any other medical conditions; are breastfeeding or plan to breastfeed; and/or are taking any other prescription or over-the-counter medicines, vitamins, and herbal supplements.

Gonal-*f*[®] RFF Redi-ject[™] may cause serious side effects, including:

- **severe allergic reactions** in women who have used Gonal-*f*[®], Gonal-*f*[®] RFF, or Gonal-*f*[®] RFF Redi-ject[™] in the past. New allergic reactions can occur immediately after an injection. Severe allergic reaction may lead to death. If you have any of the following symptoms of a severe allergic reaction, stop using Gonal-*f*[®] RFF Redi-ject[™] and go to the hospital right away: shortness of breath; swelling of your face; and/or itchy, red bumps or rash on your skin (hives)
- **ovaries that are too large**; symptoms of bloating or pain in your lower stomach (pelvic) area
- **ovarian hyperstimulation syndrome (OHSS)**; a serious medical condition that can happen when your ovaries produce too many eggs (overstimulated). OHSS can cause fluid to suddenly build up in the area of your stomach, chest, and heart and can cause blood clots to

form. In rare cases OHSS has caused death. OHSS may also happen after you stop using Gonal-*f*[®] RFF Redi-ject[™]. Stop using Gonal-*f*[®] RFF Redi-ject[™] and call your healthcare provider right away if you have symptoms of OHSS, including: trouble breathing; severe lower stomach (pelvic) area pain; decreased urine output; nausea; vomiting; weight gain; and/or diarrhea

- **lung problems**; that cause trouble breathing (acute respiratory distress syndrome, atelectasia) and worsening of asthma
- **blood clots** can cause: blood vessel problems (thrombophlebitis); stroke; loss of your arm or leg; and/or blood clot in your lung (pulmonary embolism)
- **twisting (torsion) of your ovary** if you already have certain conditions such as ovarian cysts, OHSS, pregnancy, and previous abdominal surgery. Twisting of your ovary may lead to blood flow being cut off to your ovary

Make sure you have the correct pen for your dose.

You may need to use 2 pens for certain doses. Your HCP will tell you if you need to use 2 pens.

Use your treatment diary to make sure you take the correct dose, especially if you need to use 2 pens for your dose. Your HCP should show you how to use your treatment diary, which is in your *Instructions for Use*.

For your first injection or for further injection-related guidance, please refer to the Instructions for Use. For more information, go to www.fertilitylifelines.com or call 1-866-538-7879.

Step 2 ATTACH THE NEEDLE



Remove the peel-off seal from the outer needle cap.

Place the needle on the end of the pen where you see threads and turn counterclockwise.

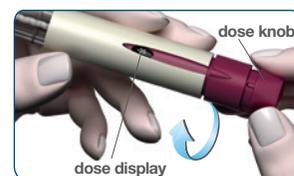


Remove the outer needle cap and set aside to use later. Leave the **blue inner needle shield** on the needle.

Step 3 INSPECT FOR LARGE AIR BUBBLES

If you see a large air bubble, a bubble that covers the entire surface of the top of the reservoir, refer to the removal instructions on the reverse side.

Step 4 SELECT THE CORRECT DOSE



Turn the dose knob clockwise until your prescribed dose shows in the **dose display**. **Do not push or pull the dose knob while you turn it.** If you pass your dose, turn the dose knob back to the correct dose.

Look at the **dose display** on the pen in bright light, like by a sunlit window or under a lamp.

Please see additional Important Risk Information continued on reverse side. Please see accompanying full Prescribing Information and Patient Information.

Step 5 SELECT THE INJECTION SITE AND INJECT YOUR DOSE



Your HCP should show you the injection sites to use around your **stomach** area. **Use a different site** each time to reduce the chance of skin problems, such as redness and irritation.

Wipe the skin with an **alcohol pad**.

Make sure the dose on the **dose display** matches your prescribed dose. Adjust to the correct dose if needed.



Carefully remove the blue inner needle shield and throw it away.



Hold the pen at a 90° angle and push the needle into your skin.

Press down on the dose knob with your thumb as far as it will go.

Wait 5 seconds before removing the needle from your skin.

Remove the needle from your skin and put the pen on the table.

Hold a **gauze pad** firmly on your injection site for a few seconds.

Step 6 COMPLETING THE INJECTION PROCESS



Do not recap the needle with the blue inner needle shield.

To remove the needle: find the **outer needle cap** and place on a flat surface. Holding the pen in 1 hand, **slip the needle into the outer needle cap without using your other hand.**



With 1 hand, push the capped needle against a surface that is firm but not slippery, like a wall, until you hear a “click.” Unscrew the capped needle by turning it clockwise.

Recap the pen with the **pen cap**.

Look at the dose display and record the number you see in your treatment diary.

Step 7 DISPOSAL OF USED NEEDLES AND EMPTY PENS



Put used needles and empty pens in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and empty pens in your household trash.**

If you do not have an FDA-cleared sharps disposal container, or for information on the proper disposal of your sharps container, please refer to the *Instructions for Use*.

IMPORTANT RISK INFORMATION (CONT.)

- **pregnancy with and birth of multiple babies** with more than 1 baby. Having a pregnancy and giving birth to more than 1 baby at a time increases the health risk for you and your babies. Your healthcare provider should tell you about your chances of multiple births
- **birth defects** in a baby born after an ART cycle (IVF or ICSI). Your chances of having a baby with birth defects may increase depending on: your age; certain sperm problems; your genetic background and that of your partner; and/or a pregnancy with more than 1 baby at a time
- **ectopic pregnancy (pregnancy outside your womb)**. Your chance of having a pregnancy outside of your womb is increased if you also have fallopian tube problems
- **miscarriage**. Your chance of loss of an early pregnancy may be increased if you had difficulty becoming pregnant
- **tumors of the ovary**. If you have used fertility medicines like Gonal-f® RFF Redi-ject™ before to get pregnant, you may have an increased chance of having tumors in your ovary(ies) (including cancer)

Please see accompanying full Prescribing Information and Patient Information.

Step 8 RECORD THE INJECTION IN YOUR TREATMENT DIARY

Unfold your treatment diary in the *Instructions for Use* and refer to the sample treatment diary entries for using 1 or 2 pens.

If your day's dose is larger than the size the pen can deliver, speak to your HCP about how to give that dose.

Treatment days 1 and 2 using 300-IU pens to give 225-IU*

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Today's Treatment Day is:	Today's Date is:	Treatment Time is:	Pen Used, (300 IU, 450 IU, or 900 IU)†:	Dose Display Set to Today's Prescribed Dose of:	After Injection, Dose Display reads "0." See Figure G in Step A. (Yes/No)	If Column 6 answer is "No," dose to set for second injection is:	Notes
1	2/14/2015	8:50 PM	300	225	Yes		Dose completed
2	2/15/2015	8:50 PM	300	225	No	50‡	Need new pen to complete prescribed dose¹
2	2/15/2015	8:52 PM	300	50	Yes		Dose completed

*This is an example of a diary for demonstration purposes only. Your actual diary entries may be different.

†The pen contains extra drug liquid to help ensure that you receive the full amount indicated on the pen (300 IU, 450 IU, or 900 IU).

‡The amount remaining to be given with the next pen may be less than expected because of the extra drug liquid. Always use the amount you have written in Column 7 to complete your dose.

To remove the used needle of 1 pen before starting a new pen to complete your prescribed dose for the day, go to **Step 6**. Then go to **Step 1 through Step 5** to complete your dose for the day with the new pen. Record your dose in your treatment diary.

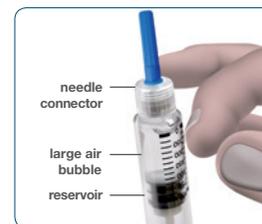
Step 9 STORE YOUR PEN

If there is medicine left, store your pen in the refrigerator or at room temperature for up to 28 days. Throw away any unused Gonal-f® RFF Redi-ject™ after 28 days.

Store your pen with the cap on in a safe place and away from light.

Do not freeze your pen. Keep your pen and all medicines out of the reach of children.

Step 3 Continued: How to remove a large air bubble



Although rare, check for large air bubbles. If you see one:

Turn the **dose knob** clockwise until the dose display reads **“.25.”** Only use .25 to remove air bubbles.

Tap the **reservoir** to allow any large air bubbles to rise to the top.



Carefully remove the blue inner needle shield and throw it away.

Holding the needle pointing up, slowly press the **dose knob** as far as it will go. Release the dose knob.

Refer to gray box in Step 6 for how to remove the needle.

Replace with a new capped needle as described in **Step 2**.

The most common side effects of Gonal-f® RFF Redi-ject™ include:

Headache; stomach pain; stomach bloating; bruising at the injection site; and nausea.

These are not all the possible side effects of Gonal-f® RFF Redi-ject™. For more information, call your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Do not share your Gonal-f® RFF Redi-ject™ and needles with another person. You may give another person an infection or get an infection from them.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Read the Patient Information found in your drug carton and talk to your healthcare provider. For more information, go to www.fertilitylifelines.com, or call 1-866-538-7879.

Also read the **Gonal-f® RFF Redi-ject™ “Instructions for Use”** that comes with pen for information about the correct use of Gonal-f® RFF Redi-ject™ and follow all training and instruction provided by your healthcare provider.