

Patient Information

Gonal-f® RFF Redi-ject® (gon-AL-eff ar-eff-eff REH dee-jekt) (follitropin alfa injection) for subcutaneous use

Gonal-f® RFF* Redi-ject® (follitropin alfa injection) for subcutaneous use

***revised formulation female**

Read this Patient Information before you start using Gonal-f® RFF Redi-ject® and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is Gonal-f® RFF Redi-ject®?

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
- cause your ovaries to make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) program

Who should not use Gonal-f® RFF Redi-ject®?

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

- are allergic to recombinant human FSH or any of the ingredients in Gonal-f® RFF Redi-ject®. See the end of this leaflet for a complete list of ingredients in Gonal-f® RFF Redi-ject®.
- 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 that may get worse with high levels of estrogen
- have a tumor in your brain, such as a tumor in your pituitary or hypothalamus
- have abnormal bleeding from your uterus or vagina
- have ovarian cysts or large ovaries, not due to polycystic ovary syndrome (PCOS)

What should I tell my healthcare provider before using Gonal-f® RFF Redi-ject®?

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 stomach (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. It is not known if Gonal-f® RFF Redi-ject® passes into your breast milk. You and your healthcare provider should decide if you will take Gonal-f® RFF Redi-ject® or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use Gonal-f® RFF Redi-ject®?

- Read the “**Instructions for Use**” that comes with Gonal-f® RFF Redi-ject® for information about the right way to use Gonal-f® RFF Redi-ject®.
- Gonal-f® RFF Redi-ject® is given by injection under your skin. Do not inject Gonal-f® RFF Redi-ject® until your healthcare provider has taught you the correct way to use it.
- Change your injection site as your healthcare provider showed you.
- Use Gonal-f® RFF Redi-ject® exactly as your healthcare provider tells you to use it.
- Do not change your dose of Gonal-f® RFF Redi-ject® unless your healthcare provider tells you to.
- Call your healthcare provider if you have any questions about your dose or how to use Gonal-f® RFF Redi-ject®.

What are the possible side effects of Gonal-f® RFF Redi-ject®?

Gonal-f® RFF Redi-ject® may cause serious side effects, including:

- **severe allergic reactions.** Women who have used Gonal-f®, Gonal-f® RFF, or Gonal-f® RFF Redi-ject® in the past may have a severe allergic reaction right away when they use Gonal-f® RFF Redi-ject® again. This 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
 - itchy, red bumps or rash on your skin (hives)

- **ovaries that are too large.** Gonal-f® RFF Redi-ject® may cause your ovaries to be abnormally large. Symptoms of large ovaries include bloating or pain in your lower stomach (pelvic) area.
- **ovarian hyperstimulation syndrome (OHSS).** Using Gonal-f® RFF Redi-ject® may cause OHSS. OHSS is 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
 - diarrhea
- **lung problems.** Gonal-f® RFF Redi-ject® may cause serious lung problems including fluid in your lungs (atelectasis), trouble breathing (acute respiratory distress syndrome), and worsening of asthma.
- **blood clots.** Gonal-f® RFF Redi-ject® may increase your chance of having blood clots in your blood vessels. Blood clots can cause:
 - blood vessel problems (thrombophlebitis)
 - stroke
 - loss of your arm or leg
 - blood clot in your lung (pulmonary embolus)
- **twisting (torsion) of your ovary.** Gonal-f® RFF Redi-ject® may increase the chance of your ovary twisting if you already have certain conditions such as OHSS, pregnancy and previous abdominal surgery. Twisting of your ovary may lead to blood flow being cut off to your ovary.
- **pregnancy with and birth of multiple babies.** Gonal-f® RFF Redi-ject® may increase your chance of having a pregnancy 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.** A baby born after an ART cycle may have an increased chance of having birth defects. 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
 - a pregnancy with more than 1 baby at a time

- **ectopic pregnancy (pregnancy outside your womb).** Gonal-f® RFF Redi-ject® may increase your chance of having a pregnancy that is abnormally outside of 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 medicines like Gonal-f® RFF Redi-ject® more than 1 time to get pregnant, you may have an increased chance of having tumors in your ovary(ies) (including cancer).

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

- headache
- stomach pain
- stomach bloating
- bruising at the injection site
- 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.

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

How should I store Gonal-f® RFF Redi-ject®?

- **Before you use Gonal-f® RFF Redi-ject® for the first time,** store your Pen:
 - in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date, or
 - store your Pen at room temperature between 68°F to 77°F (20°C to 25°C) for up to 3 months or until the expiration date, whichever comes first
- **After you use Gonal-f® RFF Redi-ject® and there is still medicine left,** store your Pen in the refrigerator between 36°F to 46°F (2°C to 8°C) or at room temperature between 68°F to 77°F (20°C to 25°C) up to 28 days. Throw away any unused Gonal-f® RFF Redi-ject® after 28 days.
- Store your Gonal-f® RFF Redi-ject® with the Pen cap on in a safe place.
- Store Gonal-f® RFF Redi-ject® away from light.
- Do not freeze Gonal-f® RFF Redi-ject®.

Keep Gonal-f® RFF Redi-ject® and all medicines out of the reach of children.

General Information about the safe and effective use of Gonal-f® RFF Redi-ject®.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Gonal-f® RFF Redi-ject® for a condition for which it was not prescribed. Do not give Gonal-f® RFF Redi-ject® to other people, even if they have the same condition that you have. It may harm them.

This Patient Information leaflet summarizes the most important patient information about Gonal-f® RFF Redi-ject®. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Gonal-f® RFF Redi-ject® that is written for health professionals.

For more information, go to www.fertilitylifelines.com, or call 1-866-538-7879.

What are the ingredients in Gonal-f® RFF Redi-ject®?

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, sodium hydroxide

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:
EMD Serono, Inc.
Rockland, MA 02370

Revised: January 2014