

Steps for Self-Injection of GONAL-F[®] RFF* Redi-ject[®]

An Easy to Use Injectible Pen[†]



Trust matters

The most prescribed r-FSH in the United States.

INDICATIONS

Gonal-f[®] RFF* Redi-ject[®] (follitropin alfa injection) is a prescription medicine containing follicle-stimulating hormone (FSH) used in infertile women to:

- help ovulation and pregnancy in women who are infertile due to a cause other than primary ovarian failure
- 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 Gonal-f[®] RFF* Redi-ject[®] if you:

- are allergic to recombinant human FSH or any of the ingredients listed on the product carton or package insert
- have levels of FSH indicating primary gonadal failure
- are pregnant or think you may be

pregnant due to the potential hazard to a fetus

- have uncontrolled thyroid, adrenal or pituitary 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
- have ovarian cysts or large ovaries with unknown cause, not due to polycystic ovary syndrome (PCOS)

Before using Gonal-f[®] RFF* Redi-ject[®], tell your healthcare provider about your medical history including any prescription or over-the-counter medicines, vitamins and herbal supplements used, whether you have or have had asthma, abdominal surgery,

ovarian cysts, polycystic ovarian disease, blood clots (thrombosis) or family history of blood clots, or are breastfeeding or plan to breastfeed.

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

- Severe or fatal allergic reactions. Stop using Gonal-f[®] RFF* Redi-ject[®] and go to the hospital right away if you have symptoms of an allergic reaction which can include shortness of breath, swelling of your face, itchy, red bumps or rash on your skin (hives).
- Stomach bloating or pain caused by enlargement of your ovaries, or fluid build-up in your stomach, chest and heart caused by ovarian hyperstimulation syndrome (OHSS). OHSS can require hospitalization and in rare cases has caused death. 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 diarrhea.

- Gonal-f[®] RFF* can also cause or worsen lung problems (including severe shortness of breath and asthma), blood and blood vessel problems (including clots and stroke) which in rare cases have caused death.
- Twisting of your ovary, which requires medical attention.
- Chances of having a baby with birth defects may increase in a baby born after an ART cycle and can be impacted by maternal age, paternal sperm problems, and genetic background associated with the egg and sperm.
- Use of Gonal-f[®] RFF* Redi-ject[®] can result in pregnancy with more than 1 baby and the birth of multiple babies.
- Ectopic pregnancy (pregnancy outside

your womb).

- An increased risk of miscarriage.
- 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).
- Ultrasound and lab tests should be used to monitor treatment.

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

- In Ovulation Induction headache, abdominal pain, and ovarian hyperstimulation

Please see Important Risk Information continued on page 2 and accompanying full Prescribing Information and Patient Information.

*RFF = revised formulation female.

How to use GONAL-F RFF* Redi-ject

Do not inject GONAL-F RFF* Redi-ject at home until your healthcare provider has taught you the right way to inject it. GONAL-F RFF* Redi-ject is for injection into the skin of the abdominal area. Choose a different injection site each day to minimize redness, irritation, or other skin problems.

Please read the following instructions carefully.

PREP:

Before you get started



Remove your medicine from the refrigerator approximately 30 minutes before you inject to let it warm to room temperature.



Wash your hands with soap and water to keep the things you use as clean as possible.

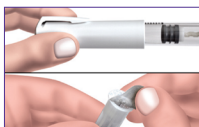


Gather everything you need on a clean, flat surface:

- one GONAL-F RFF* Redi-ject prefilled pen
- one disposable needle
- one alcohol pad
- one sharps container

[†]A study of 60 participants evaluated the study injector after receiving training. Of the participants, 23 were patients (women with infertility) and rated the injector pen for ease of use (1 = difficult and 7 = easy). Approximately, 5% of patients rated a 5, 70% rated a 6, and 25% rated a 7.

Preparing the pen



Pull off the pen cap and peel off the needle seal.

Call your healthcare provider if the pen is cracked, the liquid is discolored or cloudy, or the needle seal is broken.



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

Do not attach the needle too tightly, as it could be difficult to remove after the injection.



Pull off the outer needle cap and save it for later.



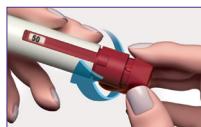
Keeping the needle pointing up, carefully pull off the green inner needle shield and throw it away.



If you're using a new pen, check for a droplet of liquid at the tip of the needle. If you don't see a droplet, follow the steps below.

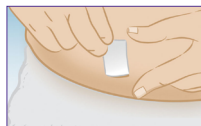
When re-using a pen, you do not need to check for a droplet. Proceed to Setting the dose. Please make sure to use a new needle provided for every injection within the package.

Setting the dose and preparing the injection site



Turn the dose knob until your intended dose shows in the dose information display.

You can turn the dose knob backward if you turn it past your intended dose. Call your healthcare provider if you are unsure of your dosage.

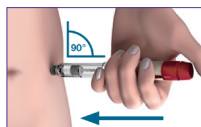


Select your injection site and wipe the skin with an alcohol pad to clean the site.

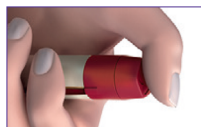
Injecting your dose



Pinch the previously cleaned skin around the injection site with one hand.



GONAL-F RFF* Redi-ject is given by injection under your skin. 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 for 5 seconds. After a slow count of 5, remove the needle from your skin and **then** release the dose knob.



You must remove the needle from the pen and throw it away after each injection to avoid risk of infection. If the pen is empty after your injection, throw it away in an FDA-cleared sharps disposal container. Do not reuse or share syringes or needles.

See FAQs for safe disposal of your pen.

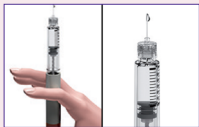
Creating a droplet of liquid



Turn the dose knob until the dose information display on the pen reads 25.



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



Keeping the needle pointing up, slowly press the dose knob in all the way until one or more tiny drops of liquid appear at the tip of the needle.



Release the dose knob and make sure the dose information display reads 0.

Completing an incomplete dose

If you've finished your injection and the dose information display on your pen does not read 0, your injection was incomplete. A second GONAL-F RFF* Redi-ject pen will be needed to finish your dose. On the new pen, dial the number that appears in the dose information display on the empty pen, then repeat the "Injecting Your Dose" step above.

MORE SUPPORT



Scan the QR code to watch an injection video for GONAL-F RFF* Redi-ject (follitropin alfa for injection).

For more support materials, visit EMDSeronoFertility.com.

FAQs

How do I properly dispose of medicine products?

All used needles, syringes, and vials should be discarded in an FDA-cleared sharps disposal container immediately after use.

If you do not have a sharps container, **do not throw away loose needles, syringes, and vials in your household trashcan.** Instead, use a container that is:

- made of heavy-duty plastic
- able to be closed with a tight-fitting, puncture-resistant lid
- upright and stable during use
- leak resistant
- properly labeled to warn of hazardous waste inside the container

For more information, visit www.fda.gov/safesharpsdisposal.

How do I know the pen is totally empty?

When your combined injected doses equal the number of IUs available in your pen and the dosing window reads 0, your device is empty. Ask your healthcare provider about keeping a treatment diary to help you keep better track of your injections.

Can I still use my medication if I left it outside in a car during hot or cold weather?

GONAL-F RFF* Redi-ject must be stored with the cap attached and away from light. New pens should be kept in the refrigerator between 36 °F and 46 °F until the expiration date, or at room temperature between 68 °F and 77 °F for up to 3 months or until the expiration date, whichever comes first.

If medicine is left in the pen after injecting, it may be stored in the refrigerator or at room temperature for up to 28 days before safely discarding.

For more information about storing your medication, call Fertility LifeLines™ support at 1-866-538-7879 or contact your healthcare provider.

IMPORTANT RISK INFORMATION (continued)

- **In ART** - abdominal pain, nausea, abdominal enlargement, headache and injection site bruising

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. Or contact EMD Serono at 1-800-283-8088.

Use Gonal-f® RFF* Redi-ject® as directed and do not change your dose unless directed. 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.

Carefully review the Gonal-f® RFF* Redi-ject® Instructions for Use that comes with the Pen for information about the correct use of Gonal-f® RFF* Redi-ject® and follow all training and instruction provided by your healthcare provider.

Please see full Prescribing Information and Patient Information for GONAL-F RFF* Redi-ject provided with this tear pad and in your product carton, or visit online. Please also see Instructions for Use (IFU) in your product carton.

*RFF = revised formulation female.