

Steps for Self-Injection of GONAL-F® Multi-Dose

A flexible approach to dosing



Trust matters

The most prescribed r-FSH in the United States.

INDICATIONS

GONAL-F® Multi-Dose is a prescription medicine containing follicle-stimulating hormone (FSH). GONAL-F Multi-Dose is used in:

Infertile women to:

- Help healthy ovaries develop (mature) and release an egg to help you get pregnant
- Cause your ovaries to make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) program

Infertile men to:

- Help develop and produce mature sperm

IMPORTANT RISK INFORMATION

Do not use GONAL-F Multi-Dose if you are a woman or man who:

- Is allergic to recombinant human FSH or any of the ingredients in GONAL-F Multi-Dose. See the end of the patient information for a complete list of ingredients in GONAL-F Multi-Dose.
- Has a high level of FSH in your blood that show your ovaries (women only) or testes (men only) do not work at all
- Has uncontrolled thyroid, adrenal or pituitary problems
- Has a tumor in your sex organs (uterus, ovaries, or testes) or breasts
- Has a tumor in your brain, such as a tumor in your pituitary gland or hypothalamus

Do not use GONAL-F Multi-Dose if you are a woman that:

- Has abnormal bleeding from your uterus or vagina from an unknown cause
- Has ovarian cysts or large ovaries from an

unknown cause

Before you start using GONAL-F Multi-Dose, tell your healthcare provider about all your medical conditions including 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

FOR WOMEN: Before you start using GONAL-F Multi-Dose, tell your healthcare provider if you:

- Have had twisting of your ovary (ovarian torsion)
- Had or have a cyst on your ovary
- Have polycystic ovarian disease
- Are pregnant or think you may be pregnant. GONAL-F Multi-Dose is not for pregnant women. Your healthcare provider will give you a pregnancy test before you start using GONAL-F Multi-Dose.
- Are breastfeeding. It is not known if GONAL-F Multi-Dose passes into your breast milk. You and your healthcare provider should decide if you will take GONAL-F Multi-Dose or breastfeed. You should not do both.
- Are not an adult. GONAL-F Multi-Dose is not for children. It is not known if GONAL-F Multi-Dose is safe or works in children.

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 Multi-Dose?

- Read the “Instructions for Use” that comes with GONAL-F Multi-Dose for information about the right way to use GONAL-F Multi-Dose.
- Use GONAL-F Multi-Dose exactly as your healthcare provider tells you to.
- GONAL-F Multi-Dose is given by injection under your skin. You can inject GONAL-F Multi-Dose under the skin in your stomach (abdomen), upper arm, or upper leg.
- **Do not** inject GONAL-F Multi-Dose at home until your healthcare provider has taught you the right way to inject it
- Change your injection site as your healthcare provider showed you
- **Do not** change your dose or the time you are scheduled to use GONAL-F Multi-Dose unless your healthcare provider tells you to
- If you miss or forget to take a dose, do not double your next dose. Ask your healthcare provider for instructions
- Your healthcare provider will do blood and urine hormone tests while you are using GONAL-F Multi-Dose. Make sure to follow-up with your healthcare provider to have your blood and urine tested when told to do so.
- Call your healthcare provider if you have any questions about your dose or how to use GONAL-F Multi-Dose.

Women:

Your healthcare provider may do ultrasound scans of your ovaries. Make sure to follow-up

with your healthcare provider to have your ultrasound scans.

Men:

Your healthcare provider may test your semen while you are using GONAL-F Multi-Dose. Make sure to follow-up with your healthcare provider to give a semen sample for testing.

What are the possible side effects of GONAL-F Multi-Dose?

GONAL-F Multi-Dose may cause serious side effects in women and men, including:

Severe allergic reactions. Women or men who have used GONAL-F Multi-Dose in the past may have a severe allergic reaction right away when they use GONAL-F Multi-Dose 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 Multi-Dose and go to the nearest hospital emergency room right away:

- Shortness of breath
- Swelling of your face
- Itchy, red bumps or rash on your skin (hives)

Lung problems. GONAL-F Multi-Dose 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 Multi-Dose may increase your chance of having blood clots in your blood vessels. Blood clots can cause:

- Blood vessel problems (thrombophlebitis)
- Stroke

How to use GONAL-F Multi-Dose

Do not inject GONAL-F Multi-Dose at home until your healthcare provider has taught you the right way to inject it. GONAL-F Multi-Dose is for injection under the skin of the stomach (abdomen) area, upper arm, or upper leg. Choose a different injection site each day to minimize irritation.

Please read the following instructions carefully.

PREP:

Before you get started



Remove your medicine from the refrigerator approximately 30 minutes before use 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:

1 one vial of GONAL-F Multi-Dose

2 one GONAL-F Multi-Dose custom dosing injection syringe (IU FSH), designed exclusively for use with this product

3 one prefilled syringe of bacteriostatic water for injection, USP (0.9% benzyl alcohol)

You'll also need:

- two alcohol swabs
- one sharps container

- Loss of your arm or leg
- Blood clot in your lung (pulmonary embolus)
- Heart attack

GONAL-F Multi-Dose may cause serious side effects in women, including:

Ovarian Hyperstimulation Syndrome (OHSS).

OHSS is both a serious and common side effect. Using GONAL-F Multi-Dose 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 Multi-Dose. Stop using GONAL-F Multi-Dose and call your healthcare provider right away if you have symptoms of OHSS, including:

- Trouble Breathing
- Severe Lower Stomach (Pelvic) Area Pain
- Weight Gain
- Nausea
- Vomiting
- Diarrhea
- Decreased Urine Output

Twisting (torsion) of your ovary. GONAL-F Multi-Dose may increase the chance of your ovary twisting if you already have certain conditions such as OHSS, pregnancy and previous

Please see Important Risk Information continued on page 2 and accompanying full Prescribing Information, Patient Information and Instructions for Use (IFU).

Mixing the powder and water to make up your medicine



Using your thumb, flip off the plastic cap of the vial and wipe the top of the vial stopper with an alcohol pad.



Carefully twist and pull off the protective cap of the prefilled syringe of bacteriostatic water.

Do not touch the needle or allow it to touch any surface.



Holding the vial upright with the bottom on a flat surface, insert the needle straight down through the center circle marked on the vial's rubber stopper.



Slowly inject the water into the vial by pressing down on the syringe plunger.



Gently rotate the vial between your fingers until the powder is dissolved. **Do not shake.** When all of the water has been injected into the vial, remove your finger from the syringe plunger and withdraw the needle from the vial.



Immediately throw away (dispose of) the needle and syringe into your FDA-cleared sharps container.

Do not use this needle or syringe to inject your dose.

See FAQs for safe disposal of used needles, vial, and syringe.

Preparing the dose and injection site



Do not use the GONAL-F Multi-Dose liquid solution if it contains any particles. Report this to your doctor, nurse, or pharmacist immediately. Do not touch the needle or allow it to touch any surface.

Wipe the rubber stopper of the vial with an alcohol swab. Remove the wrapper and carefully pull the needle cap off the custom dosing injection syringe.



Firmly hold the vial on a flat surface and insert the needle through the marked center circle of the rubber stopper.



While keeping the needle inserted, turn the vial upside down so that the needle points towards the ceiling.



Slowly pull back the plunger until the syringe fills slightly past the mark for your prescribed dose.



Slowly push the plunger to your prescribed dose and until all air bubbles are gone and a drop of liquid appears on the tip of the needle. Then, remove the syringe needle from the vial and recap the needle and set on a clean, flat surface. The syringe is now ready for administration.

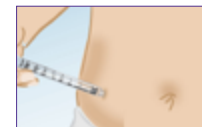


Choose an injection site. Clean the skin at your chosen site with the second alcohol swab.

Injecting your dose



Uncap the syringe, then pinch the previously cleaned skin around the injection site with one hand.



GONAL-F Multi-Dose is given by injection under your skin. Insert the entire length of the needle into the skin at a 90° angle, then release the pinched skin. Slowly depress the plunger until all medication is injected.



Remove the needle from your skin and properly dispose of all needles, syringes, and vials in your sharps container. Do not reuse or share syringes or needles.

See FAQs for safe disposal of used needles, syringes, and vials.

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.

What do I do if I have used too much GONAL-F Multi-Dose?

Contact your doctor if you take more than the prescribed amount of GONAL-F or experience severe pain or bloating in the stomach or pelvic area, severe stomach upset, vomiting, and weight gain.

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

GONAL-F Multi-Dose must be stored away from light. Vials (mixed or unmixed) can be stored in the refrigerator or at room temperature between 36 °F and 77 °F. Safely discard any mixed solution after 28 days. 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)

abdominal surgery. Twisting of your ovary may lead to blood flow being cut off to your ovary.

Ovaries that are too large. GONAL-F Multi-Dose may cause your ovaries to be abnormally large. Symptoms of large ovaries include bloating or pain in your lower stomach (pelvic) area.

Pregnancy with and birth of multiple babies.

GONAL-F Multi-Dose 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 one baby at a time

Ectopic pregnancy (pregnancy outside your womb).

GONAL-F Multi-Dose 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. Call your healthcare provider right away if you have symptoms of an ectopic pregnancy including:

- Stomach or pelvic pain, especially on one side
- Shoulder pain
- Neck pain
- Rectal pain
- Nausea and vomiting

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 Multi-Dose more than one time to get pregnant, you may have an increased chance of having tumors in your ovary(ies) (including cancer).

Common side effects of GONAL-F Multi-Dose include:

In Women:

- Ovarian Cyst
- Headache
- OHSS
- Stomach pain

- Pelvic pain
- Nausea
- Gas
- Bleeding in between periods

In Men:

- Skin Problems
- Breast Enlargement
- Injection site pain
- Seborrhhea
- Tiredness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of GONAL-F Multi-Dose. For more information, ask your healthcare provider or pharmacist.

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

Please see full Prescribing Information, Patient Information and IFU for GONAL-F Multi-Dose provided with this tear pad and in your product carton, or visit online.