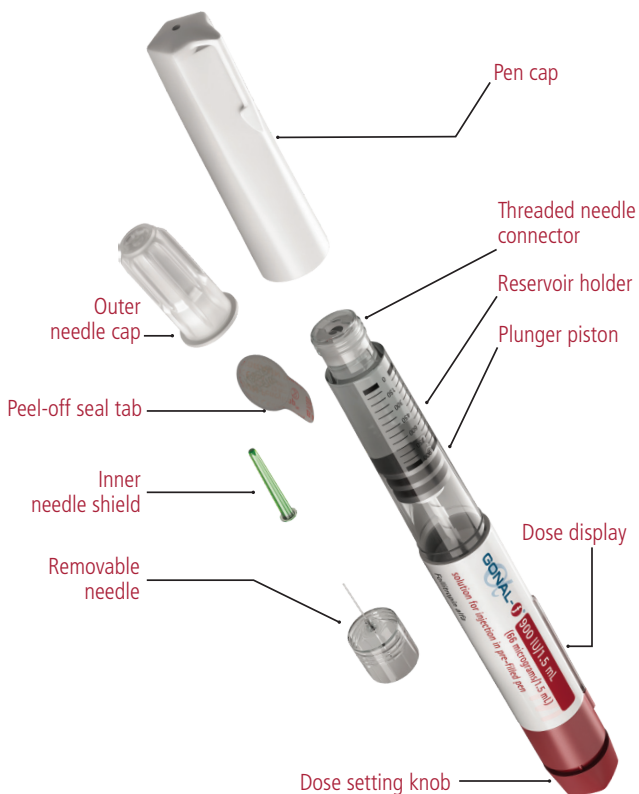


PATIENT INSTRUCTIONS FOR THE GONAL-*f*[®] PEN



GONAL-*f*[®] PEN

AVAILABLE IN:

300 IU/0.5 mL (22 µg/0.5 mL)

450 IU/0.75 mL (33 µg/0.75 mL)

900 IU/1.5 mL (66 µg/1.5 mL)



Step 1: Before you start using your GONAL-*f*® Pen



WARNING: Do not shake the pen, as this may cause air bubbles to appear in the medication.



IMPORTANT: Verify the **expiration date** on the pen label. Do not use expired medication.

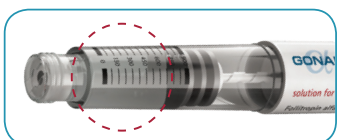
- Wash your hands with soap and water. It is important that your hands and items you use be as clean as possible.
- Take the carton out of the refrigerator for at least 30 minutes before use to let it warm to room temperature. Do not use a microwave or other heating element to warm up the pen.
- On a clean surface, e.g., clean table or kitchen surface, lay out everything you will need:

1. GONAL-*f*® Pen
2. One removable injection needle (1/2 inch 29 gauge) [use the single-use disposable needles provided with the GONAL-*f*® Pen box]
3. Alcohol swabs
4. Sharps disposal container (not shown)

Step 2: Getting your GONAL-*f*® Pen ready for injection



- Take off the pen cap.
- Wipe the end of the threaded tip (containing the rubber centre) using an alcohol swab.



- Look carefully at the reservoir holder. Check that the reservoir holder is not cracked and that the solution is clear and does not contain particles. If the reservoir holder is cracked or if the solution is discoloured or cloudy, obtain a new pen.



- Verify that the dose display is set to "0".



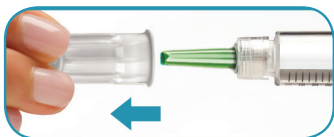
- Take out a new injection needle. Again, only use the "single-use" needles supplied.
- Hold the outer needle cap firmly.
- Check that the peel-off seal on the outer needle cap is not damaged or loose.
- Remove the peel-off seal.

CAUTION: If the peel-off seal is damaged or loose, do not use the needle. Throw it away in a sharps disposal container. Get a new needle.

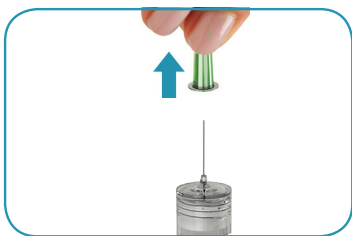
Step 3: Attach the needle



- Press the threaded tip of the pen into the outer needle cap and twist it clockwise until you feel a light resistance. Do not attach the needle too tightly though, or it might be hard to take it off again.



- Remove the outer needle cap by pulling it straight off.
- Put it aside for later use.
- Do not throw away the outer needle cap; you will need it for removing the needle from the pen.



- Hold the GONAL-*f*® Pen with the needle pointing upwards.
- Carefully remove the green inner shield by pulling it straight off and discard it.

WARNING: Do not recap the needle with the green inner shield as this can lead to needle stick.

IF THIS IS A BRAND NEW PEN THAT YOU ARE USING FOR THE FIRST TIME LOOK CLOSELY AT THE TIP OF THE NEEDLE FOR A TINY DROP OF FLUID.

- If you see a tiny drop(s) of fluid, move on to Step 4.
- If you do not see a tiny drop(s), here's what you need to do:



- Gently turn the dose setting knob clockwise until it reads "25" in the dose display. You can turn the dose knob backwards if you turn it past "25".

- Hold the pen with the needle pointing upward.

- Tap the reservoir holder gently.
- Press the dose setting knob down as far as it will go. A tiny drop of fluid will appear at the tip of the needle. The amount of fluid seen at the needle tip is part of the overfill from the pen.
- Verify that the dose display reads "0".

You may need to repeat this step if you do not see a tiny drop of liquid appearing at the tip of the needle.

Once you see the tiny drop of liquid at the tip of the needle proceed to Step 4 "Setting your dose."

Step 4: Setting your dose



- Turn the dose setting knob forward (or clockwise) until your prescribed dose shows in the dose display. Do not push or pull the dose setting knob while you turn it.

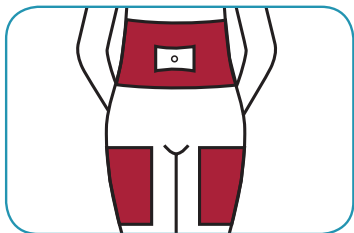
IMPORTANT: To avoid breaking the pen, *ONLY* twist the end of the dose setting knob.



- If you have turned the knob past your prescribed dose, turn the knob backwards (or counterclockwise) to correct the dose.

IMPORTANT: Check that the dose display shows your prescribed dose before you move on to the next step.

Step 5: Injecting the dose



- Select an injection site as your doctor has told you to, such as the upper thigh or abdomen, using the injection site diagram.
- Choose a different site each day to minimize skin irritation.



- Using an alcohol wipe, clean the injection site (about 5 cm x 5 cm).
- Allow the alcohol to dry.
- Set the alcohol wipe to the side.

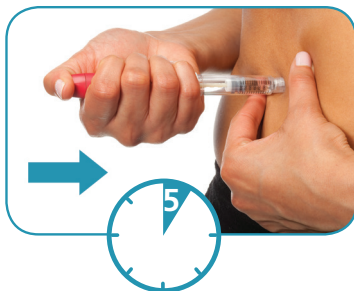
Step 5: Injecting the dose (cont'd)



- Check again the dose shown in the dose display. If it is not the correct dose, you must adjust it by turning the dose setting knob either clockwise or counterclockwise.



- Inject the dose as you were trained to do by your doctor or nurse. Hold the pen in one hand and use your other hand to gently squeeze the skin together to make a raised area at the injection site.
- Insert the needle at a 90-degree angle into the skin and press the injection button down as far as it will go. You might bend the needle if you do not inject at a 90-degree angle.



- You must keep the needle in the skin with the injection button pressed down for at least 5 seconds to ensure you inject the full dose. The larger the dose, the longer it will take to inject. After 5 seconds, keep the injection button pressed down while removing the needle from your skin.
- Release the dose setting knob.

IMPORTANT: Do not release the dose setting knob until after you remove the needle from your skin.



- When you are done injecting, use the clean side of your alcohol swab to gently clean the injection site. If there is minor oozing you may need to apply a small amount of pressure for a few seconds.

Step 6: After injecting



- Now that you've finished your injection, you'll need to make sure that you've injected your full dose. The dose window should show "0".
- If the display shows a number higher than "0", this means the pen is empty and the full prescribed dose has not been given.
- The number shown in the dose display is the missing amount that you'll have to inject using a new pen. If that happens, prepare a new pen like your doctor or nurse has shown you, and set the dose to the exact number displayed on the dose display of the empty pen. Now you are ready to complete your daily dose.
- Make sure you check for tiny drops of fluid if you are using a brand new GONAL-*f*® Pen for the first time.

IMPORTANT: Always make sure to use a new needle for each injection.

REMOVING THE NEEDLE AFTER EACH INJECTION:

- Place the outer needle cap on a flat surface.
- Hold the GONAL-*f*® Pen firmly with one hand, and slip the needle into the outer needle cap. Be careful not to prick yourself with the needle.
- Continue by pushing the capped needle against a firm surface until you hear a "click."
- Grip the outer needle cap and unscrew the needle by turning counterclockwise. Dispose of the used needle safely.
- Never reuse any used needle. Never share needles.



- Please note that your clinic may provide you with a special sharps container designed for GONAL-*f*®. If you have received the special GONAL-*f*® sharps container, simply follow the steps to remove the needle that are outlined on the box.
- Recap the pen and store the pen as instructed.

CAUTION: Never store the pen with the needle attached. Always remove the needle from the GONAL-*f*® Pen before replacing the pen cap.

For more information on GONAL-*f*® please refer to the package insert that came with your medication.

Frequently Asked Questions

What is GONAL-*f*®?

- GONAL-*f*® is follicle-stimulating hormone (FSH) with no urinary proteins, which stimulates oocyte (egg) development in women. GONAL-*f*® is a highly purified recombinant form of FSH, manufactured using the latest technology with proven effectiveness and safety in clinical studies.
- GONAL-*f*® is provided in liquid formulation in a pen, for easy administration under the skin (subcutaneous injection).
- GONAL-*f*® belongs to a group of medicines called “gonadotropins”.

What is GONAL-*f*® used for?

- GONAL-*f*® (follitropin alpha for injection) is used to stimulate the maturation of follicles in ovulating patients undergoing Assisted Reproductive Technologies (ART), such as *in vitro* fertilization (IVF).
- GONAL-*f*® is also used to stimulate the maturation of follicles in some patients whose menstrual cycle is either irregular or absent. In both cases, another hormone, hCG (human chorionic gonadotropin) is given to complete the maturation of follicles.

When should GONAL-*f*® not be used?

GONAL-*f*® should **not** be used if you:

- Have high levels of FSH indicating primary ovarian failure
- Have uncontrolled thyroid or adrenal dysfunction
- Are allergic (hypersensitive) or have a history of hypersensitivity to FSH or to any of the other ingredients of GONAL-*f*®
- Are pregnant or breastfeeding
- Have ovarian enlargement or a cyst not due to polycystic ovarian disease (PCO)
- Have vaginal bleeding of unknown cause
- Have tumours of the ovary, uterus, breast or brain (hypothalamus or pituitary gland)

What are some side effects I could see with GONAL-*f*® therapy?

Fertility drugs are safe to take with close monitoring by your doctor. As with all medication, there is a potential for side effects.

The following side effects have been reported with the use of GONAL-*f*® during clinical trials and post-market use:

Common and Very Common: may affect 1 to 10 users in 100

- Ovarian cysts
- Mild to moderate ovarian enlargement
- Breast tenderness

- Mild to moderate ovarian hyperstimulation syndrome (OHSS)
- Mild to severe injection site reaction (such as pain, redness, bruising, swelling and/or irritation)
- Headache
- Stomach pain or bloating
- Feeling sick (nausea), vomiting, diarrhea

Uncommon, Rare and Very Rare: may affect less than 1 to 10 users in 1,000

- Severe OHSS
- Blood clots (thrombosis)
- Difficulty breathing (acute pulmonary distress)
- Worsening of asthma
- Mild to severe allergic reactions (hypersensitivity) such as rash, red skin, hives, swelling of your face with difficulty breathing may occur. These reactions can sometimes be serious.

The greatest concern your doctor will have is OHSS. To avoid the development of OHSS, your doctor will carefully monitor your response to GONAL-*f*[®]. Ovarian enlargement, sometimes accompanied by abdominal bloating and pain, may occur in about 20% of women taking gonadotropins. This is generally reversed with cessation of treatment and severe life-threatening cases are rare.

A causal relationship between treatment with fertility drugs and ovarian cancer has not been established.

The following medical events have been reported subsequent to pregnancies resulting from gonadotropin therapy in controlled clinical trials: spontaneous abortion, tubal pregnancy, premature labour, postpartum fever and congenital abnormalities.

None of these events were thought to be drug-related. The incidence is not more than that found in the general population.

This is not a complete list of side effects. If you experience any unusual symptoms or side effects while taking GONAL-*f*[®], you should report them to your doctor or pharmacist immediately. It is also wise to discuss the possibility of side effects with your doctor before you begin treatment.

What are the interactions with this medication?

- GONAL-*f*[®] is often used with other medicines to stimulate ovulation (e.g., hCG and lutenizing hormone [LH]) which may help the maturation of follicles, which contains the eggs. If a GnRH agonist or antagonist medicine is also given along with your GONAL-*f*[®] in your treatment program, you may be told by your doctor to change your dose of GONAL-*f*[®] over the course of your treatment.
- No other significant interactions with other medicines have been reported.

What is the recommended dose?

- Every treatment is individualized. Your treatment has been carefully designed for you by your doctor. Over the course of your treatment, doses may range between 75 to 450 IU depending on your specific medical condition and your response to the medicine.

What do I do if I missed a dose or overdose?

- Missed dose: Do not take a double dose to make up for any you have missed. Contact your doctor for advice if you forget to take a dose of GONAL-*f*[®].
- Overdose: If you have accidentally injected too much GONAL-*f*[®], do not panic. Simply contact your physician or healthcare professional for further instructions.

IMPORTANT: The maximum dose that can be dialed is 450 IU for the 900 & 450 IU Pen & 300 IU for the 300 IU Pen.

How should I store my GONAL-*f*[®] Pen at home?

- 2-8°C (in a refrigerator) or store for a single period between 2 and 25°C (in the refrigerator or at room temperature) for a maximum of 3 months.
- After first use, the pen may be stored at 25°C (room temperature) for a maximum of 28 days.
- Do not use the GONAL-*f*[®] Pen if the solution contains particles or is not clear.
- Do not freeze.
- Protect the GONAL-*f*[®] Pen from light.
- Keep in a safe place out of the reach of children.
- Do not use after the expiry date.

What should I do when I cannot push the injection button to deliver the dose?

- When you cannot push the injection button down, it means your pen is empty and it is unable to provide you with your desired dose. You may still see a small amount of medication remaining in the pen. This is normal.

What do I do if there is not enough GONAL-*f*[®] remaining in the pen for my prescribed dose?

- If the dose display shows a number higher than “0” after your injection, this indicates that the pen is empty and that the complete dose has not been given. If this happens, the number shown in the dose display indicates the missing amount of GONAL-*f*[®] solution that is needed to complete your dose. This is the dose you need to inject using a new pen.
- To complete your dose, follow the steps described in previous pages to set the dose to the missing amount displayed on the empty pen that you have just finished, and proceed with the injection.

What do I do if I dialed the wrong dose?

- If you pass your dose, turn the injection button back to the correct dose. To adjust the dose, you can turn the injection button either clockwise or counterclockwise. After confirming the correct dose from the display window, you can proceed with the injection.

Looking for support? You are not alone.



MOMENTUM is a free and confidential patient services program that offers customized support, including injection assistance – available to individuals using EMD Serono fertility products.

Contact *MOMENTUM*:



1-800-387-8479



fertility.mymomentum.ca

Call *MOMENTUM* between the hours of 8:00 a.m. and 8:00 p.m. (Eastern Time), Monday to Friday. *MOMENTUM* is available 24 hours a day, 7 days a week for urgent inquiries that cannot wait until the following business day. Simply leave your name, reason for calling, and phone number, and a registered nurse will return your call in a timely manner.

MOMENTUM will not comment on individual diagnosis or treatment questions, or laboratory results. You should discuss those with your healthcare provider. *MOMENTUM* is a source of educational support sponsored by EMD Serono, Canada and is not intended to replace discussions with your healthcare provider.



Reference: GONAL-*f*® Product Monograph. EMD Serono, May 1, 2017.

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