

STEP 1: Getting prepared



Lay out the following materials on a clean surface.

1. GONAL-[®] Pen
2. Removable Needle
3. Alcohol Wipes
4. Needle disposal container (your clinic may have provided you with one).

Wash your hands with soap and water.



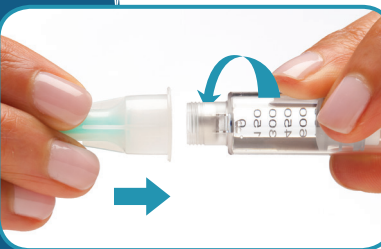
Take the cap off of the pen.



Wipe the threaded tip with an alcohol wipe.

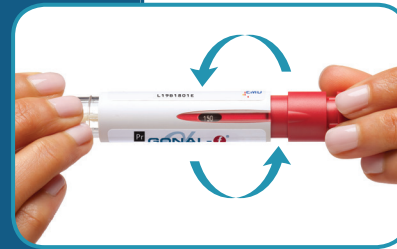


Remove the peel tab from the outer needle cap.



Press the threaded tip of the pen into the outer needle cap and twist it clockwise until it is securely fixed.

STEP 2: Setting your dose



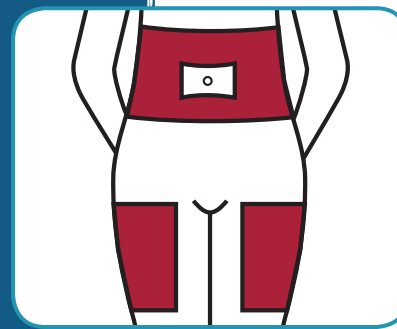
Gently turn the injection button clockwise until you can read your dose through the dose display. Do not push or pull the injection button while you turn it.



If you pass your dose, simply turn the injection button back to the correct dose. To adjust the dose, you can turn the dose dial either clockwise or counter-clockwise.

STEP 3: Injecting your medication

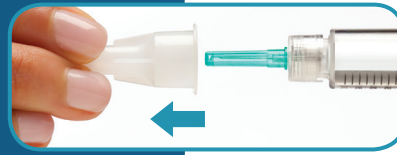
IMPORTANT: If you see a large air bubble inside the reservoir you need to remove it. Refer to "Removing large air bubbles" section for further instructions. An air bubble is large if it fills fully the tip of the reservoir when holding the pre-filled Pen with the needle pointing upwards. Small air bubbles that stick to the inner wall of the reservoir do not need to be removed. They are not harmful.



Select an injection site, such as the upper thigh or abdomen, using the injection site diagram. Choose a different site each day.



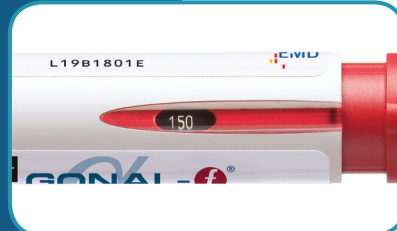
Using an alcohol wipe, clean the injection site. (About 5 cm x 5 cm) Allow the alcohol to dry.



Remove the outer needle cap. (Do not throw away the outer needle cap; you will need it for removing the needle from the Pen.)



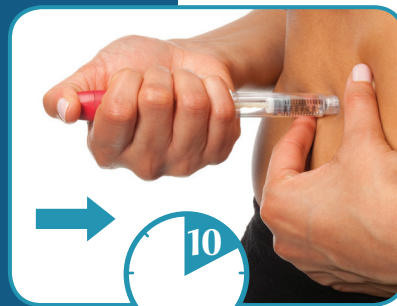
Remove the inner needle cap from the needle.



Check again the dose shown in the dose display. If it is not the correct dose, you must adjust it by turning the injection button either clockwise or counter-clockwise (see Step 2 "Setting your dose").



Holding the pen in one hand, use your other hand to gently squeeze the skin together to make a raised area at the injection site. Use the injection technique as advised by your medical practitioner or nurse.



Slowly insert the needle at a 90-degree angle into the skin and press the injection button as far as it will go. You must keep the needle in the skin with the injection button pressed down for at least 10 seconds.

After 10 seconds, keep the injection button pressed down while removing the needle from your skin.

STEP 4: After injecting



The dose number shown in the dose display will turn back to 0. This indicates that the complete dose was delivered.

If the dose display shows a number higher than 0, 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-[®] solution that is needed to complete your dose. This is the dose you need to inject using a new Pen.



Using a clean alcohol wipe, gently clean the injection site.

Apply a small amount of pressure for a few seconds if there is minor oozing (discharge).



Remove the needle after each injection.

Hold the pen firmly by the reservoir holder.

Carefully replace the outer needle cap onto the needle.

Grip the outer needle cap and unscrew the needle – do this by turning it counter-clockwise.

Be careful not to prick yourself with the needle.



Dispose of the used needle safely (ask your health care providers how to dispose of needles that are no longer required).

Put the pen cap back onto the pen. Never reuse or share any needles.

Removing large air bubbles

If you see a large air bubble inside the reservoir you need to remove it. An air bubble is large if it fills fully the tip of the reservoir when holding the pre-filled pen with the needle pointing upwards.

IMPORTANT: You do not need to remove small air bubbles that stick to the inner wall of the reservoir. They are not harmful.



Gently turn the injection button clockwise until it reads 25 IU preceded by a dot (•) in the dose display. If you pass this position, simply turn the injection button back to 25 and dot (•).



Carefully remove the outer needle cap and the inner needle shield and hold the pen with the needle pointing upwards. [Do not throw away the outer needle cap; you will need it for removing the needle from the pen.]

Tap the reservoir holder gently with your finger so that any air bubbles rise up towards the needle. With the needle still pointing upwards, slowly press the dose setting knob as far as it will go.



A drop of liquid must appear at the tip of the needle; this shows that your Pen is ready for injection. The amount of liquid seen at the needle tip is part of the overfill from the pen.

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® contains no urinary proteins.

GONAL-f® is provided in liquid formulation in a prefilled Pen, for easy administration under the skin (subcutaneous injection).

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 are hypersensitive to FSH or to any of the other ingredients of GONAL-f®;
- you have tumours of the hypothalamus and pituitary gland;
- you are pregnant or breastfeeding;
- you have ovarian enlargement or a cyst not due to polycystic ovarian disease (PCO);
- you have gynaecological bleeding of unknown cause;
- you have ovarian, uterine or breast cancer.

How is GONAL-f® administered?

Due to its high level of purity, GONAL-f® is approved for subcutaneous injection (just under the skin), which is easier and less painful than intramuscular injections (in the muscle).

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: The effects of overdose are unknown. Contact your doctor for advice if you take more than your prescribed dose of GONAL-f®.

Should I be concerned about interactions with other medications?

GONAL-f® is often used with other medicines to stimulate ovulation (e.g., hCG, lutenizing hormone [LH], and clomiphene citrate), which may help the maturation of follicles, or a GnRH (gonadotropin-releasing hormone) medication can also be given along with GONAL-f® in your treatment program. No other significant interactions with other medicines have been reported.

What are the main side effects I could see with GONAL-f® therapy?

As with all medication, there is a potential for side effects with GONAL-f® therapy. Some patients undergoing gonadotropin therapy may experience some breast tenderness, fatigue, bloating, weight gain, nausea or diarrhea. These are temporary and will resolve once treatment is stopped. Other adverse reactions may include allergic sensitivity such as a rash and local swelling at the injection site.

The greatest concern your doctor will have is ovarian hyperstimulation syndrome (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.

This is not a complete list of side effects. If you experience any unusual symptoms or side effects, you should report them to your doctor immediately.

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

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

- Store your GONAL-f® Pen between 2° and 25° C (in refrigerator or at room temperature) for a single period of up to three months. Do not freeze.
- After first use, store your Pen at room temperature for up to 28 days.
- Do not use the GONAL-f® Pen if the solution contains particles or is not clear.
- Protect the GONAL-f® Pen from light.
- Do not use the GONAL-f® Pen after its expiry date.
- Keep in a safe place out of reach of children

* GONAL-f is a registered trademark of Ares Trading S.A, used with permission.

Where can I get help and find more information?

The MOMENTUM patient services program (formerly Fertility Lifelines) is a free and confidential service that offers customized patient support, including injection assistance, to individuals using EMD Serono fertility products.

Call MOMENTUM toll-free at **1-800-387-8479** 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 your phone number, and a registered nurse will return your call in a timely manner. MOMENTUM is available in over 250 languages through the assistance of certified translators.

MOMENTUM is also available online at fertility.mymomentum.ca.

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

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.

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1-800-387-8479

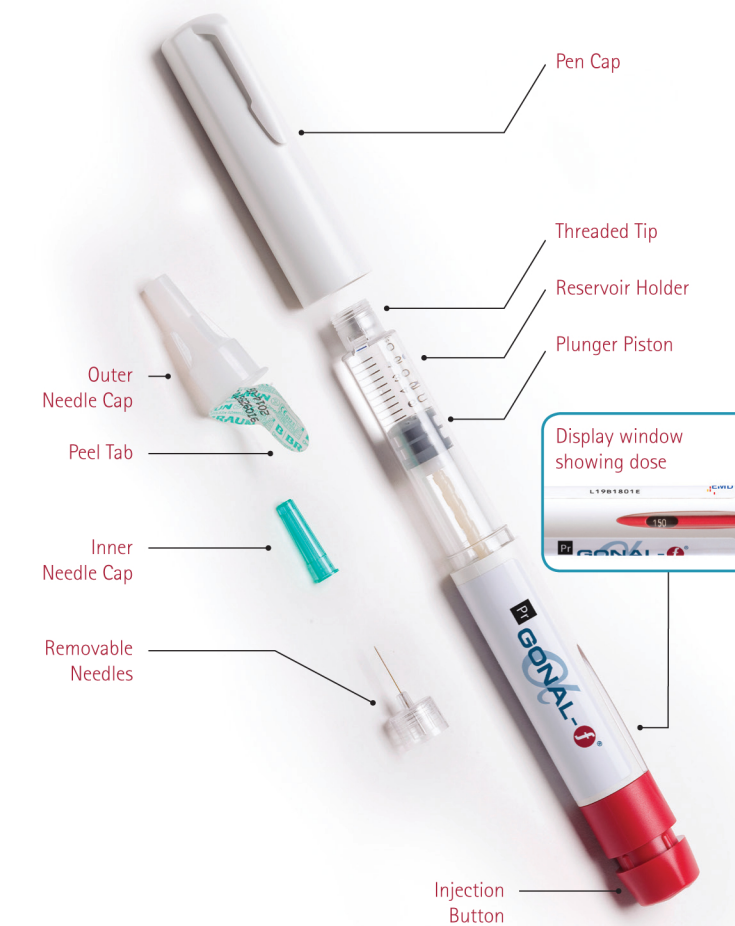
MOMENTUM is a complimentary and confidential phone service which offers support for patients who are prescribed EMD Serono fertility products.



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GONAL-f®
(Follitropin alpha injection, rDNA origin)
Pen

PATIENT INSTRUCTIONS FOR THE GONAL-f® PRE-FILLED PEN



GONAL-f® pen available in:

- 300IU/0.5mL (22µg/0.5mL)
- 450IU/0.75mL (33µg/0.75mL)
- 900IU/1.5mL (66µg/1.5mL)

