GONAL-f® PRE-FILLED PEN
900 IU/1.5 mL

Instructions for use

Merck

125

GONAL-f® 900 IU/1.5 ml
(66 micrograms/1.5 ml)

Contents

⚠️ **Warning:** Please read these instructions for use before using your GONAL-f pre-filled pen. Follow the procedure exactly, as it may differ from your past experience.

1. How to use the GONAL-f pre-filled pen

- Do not share the pen. The pen is for subcutaneous injection only.
- The numbers on the **Dose Feedback Window** are measured in International Units or IUs. Your doctor will have told you how many IUs to inject each day.
- The numbers displayed in the **Dose Feedback Window** help you to:

  a. Dial your prescribed dose.

  b. Verify a complete injection.

  c. Read the dose remaining to be injected with a second pen.

- Give yourself the injection at the same time each day.

- Your doctor/pharmacist will tell you how many pens you need to complete your treatment.

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2. How to use your GONAL-f pre-filled pen Treatment Diary

A treatment diary is included on the last page.
Use the treatment diary to record the amount of injected IUs you use each time.

- Record the treatment day number (1), date (2) and time (3) of your injection.
- In the first line of the table the volume of your pen is already recorded for you (4).
- Record your prescribed dose in the "Prescribed Dose" section (5).
- Verify you dialed the right dose before injecting (6).
- After injection, read the number shown in the **Dose Feedback Window**.
- Confirm you receive a complete injection (7) or record the number shown in the **Dose Feedback Window** if other than "0" (8).
- When needed, inject yourself using a second pen, dialing your remaining dose written in the "Amount Displayed After Injection" section (8).
- Record this remaining dose in the **"Amount Set to Inject"** section in the next row (6).

> **CAUTION:**
>
> *Using your treatment diary to record your daily injection(s) allows you to verify every day that you received the full prescribed dose.*

An example of a treatment diary:

1 Treatment Day Number	2 Date	3 Time	4 Pen Volume 900 IU/1.5 mL	5 Prescribed Dose	6	7	8
						Dose Feedback Window	
					Amount Set to Inject	Amount Displayed After Injection `0`	
#1	10|06	07:00	900 IU	350	350	☑ if "0", injection complete	☐ if not "0", need second injection Inject this amount ....using new pen
#2	11|06	07:00	900 IU	350	350	☑ if "0", injection complete	☐ if not "0", need second injection Inject this amount ....using new pen
#3	12|06	07:00	900 IU	350	350	☐ if "0", injection complete	☑ if not "0", need second injection Inject this amount .150.using new pen
#3	12|06	07:00	900 IU	N/A	150	☑ if "0", injection complete	☐ if not "0", need second injection Inject this amount ....using new pen

Note: The 300 IU pen maximum single-dose setting is 300 IU; the 450 IU pen maximum single-dose setting is 450 IU; the 900 IU pen maximum single-dose setting is 450 IU.

3. Before you start using your GONAL-f pre-filled pen

- Wash your hands with soap and water.
- Find a clean area **and a flat surface.**
- Verify the **expiration date** on the pen label.
- Gather everything you need and lay it out:

Lot: 123456
EXP: JUL 2019
L19Y0003A

1. Dose setting knob
2. **Dose Feedback Window**
3. Plunger piston
4. Reservoir holder
5. Threaded needle connector
6. Pen cap
7. Peel-off seal tab
8. Removable needle
9. Inner needle shield
10. Outer needle cap
11. Alcohol swabs
12. Sharps disposal container

4. Getting your GONAL-f pre-filled pen ready for injection

4.1. Take off the pen cap

4.2. Verify that the Dose Feedback Window is set to ''0''.

4.3. Prepare your needle for injection

- Get a new needle – 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.

Example of a good seal

Example of a bad 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.

4.4. Attach the needle

- Screw the threaded tip of the GONAL-f pre-filled pen into the outer needle cap until you feel a light resistance.

⚠️ **Warning:** Do not attach the needle too tightly; the needle could be difficult to remove after the injection.

- Remove the outer needle cap by pulling it gently. **Put it aside for later use.**

- Hold the GONAL-f pre-filled pen with the needle pointing upward.

- Carefully remove and discard the green inner shield.

4.5. Look closely at the tip of the needle for tiny drop(s) of fluid

- If you see a tiny drop(s) of fluid proceed **to Section 5: Setting the dose prescribed by your doctor.**

⚠️ **Warning: ONLY** check for drop(s) the **FIRST TIME** you use a new GONAL-f pre-filled pen to remove air in the system.

CAUTION:

*If you do not see a tiny drop(s) at or near the needle tip **the first time** you use a new pen, you must perform the steps on the next page.*

If you do not see a tiny drop(s) of fluid at or near the tip the first time you use a new pen:

1. Gently turn the dose setting knob clockwise until it **reads 25** in the Dose Feedback Window. You can turn the dose knob backwards if you turn it past 25.

2. Hold the pen with the needle pointing upward.
3. Tap the reservoir holder gently.
4. Press the dose setting knob **as far as it will go**. A tiny drop of liquid will appear at the tip of the needle.
5. Verify that the Dose-Feedback Window reads "0".
6. Proceed **to Section 5: Setting the dose prescribed by your doctor.**

5. Setting the dose prescribed by your doctor

5.1. The pen contains 900 IU follitropin alpha.

- The 900 IU pen **maximum single-dose setting is 450 IU** and the smallest single-dose setting is 12.5 IU.

5.2. Turn the dose setting knob until your intended dose shows in the Dose Feedback Window.

- Turn the dose setting knob **forward** to dial up

- Turn the dose setting knob **backward** to correct the dose

5.3. Set the dose that was prescribed by your doctor (in the example shown in the figure, it is 50 IU).

⚠ **Warning:** Check that the Dose Feedback Window displays your **complete prescribed dose** before you move on to the next step.

6. Injecting the dose

6.1. Choose an injection site in the area your doctor or nurse has told you to give the injection. To minimize skin irritation, select a different injection site each day.

6.2. Clean the skin by wiping with an alcohol swab.

6.3. Verify once more that the Dose Feedback Window displays the correct dose.

Injection area

6.4. Inject the dose as you were trained to do by your doctor or nurse.
- Slowly push the needle into the skin entirely (1).
- **Press the dose knob down as far as it will go** and hold it to complete the full injection.

1 Push the needle into the skin

- Hold the dose knob down for a minimum of 5 seconds to ensure you inject the full dose (2). The larger the dose, the longer it will take to inject.
- The dose number shown in the Dose Feedback Window will turn back to 0.

- After a minimum of 5 seconds, pull the needle out of the skin **while keeping the dose setting knob pressed down** (3).
- Release the dose setting knob.

⚠️ **Warning:** Always make sure to use a new needle for each injection.

7. After the injection

7.1. Verify you have given a complete injection.

- Check that the Dose Feedback Window shows "0".

⚠️ **Warning:** If the **Dose Feedback Window** shows a number higher than 0, the GONAL-f pre-filled pen is empty and you have not received your full prescribed dose.

7.2. Complete a partial injection (only when needed).
- The **Dose Feedback Window** will indicate the missing amount you need to inject **using a new pen.**

- Repeat Section 3 **("Before you start using your GONAL-f pre-filled pen")** through Section 4 **("Getting your GONAL-f pre-filled pen ready for injection")** with a second pen.
- Set the dose to the missing amount you recorded in the treatment diary or the number still displayed in the Dose Feedback Window on your previous pen, and inject

7.3. Removing the needle after each injection.

- Place the outer needle cap on a flat surface.
- Hold the GONAL-f pre-filled pen firmly with one hand, and slip the needle into the outer needle cap.

- Continue by pushing the capped needle against a firm surface until you hear a "click."

click

- Grip the outer needle cap and unscrew the needle by **turning anti-clockwise.** Dispose of the used needle safely.

- Never reuse any used needle. Never share needles.
- Recap the pen.

7.4. Storing the GONAL-f pre-filled pen.

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

- Store the pen in its original packaging in a safe place.
- When the pen is empty, ask your pharmacist how to dispose of it.

⚠️ **Warning:** Medicine should not be disposed of via wastewater or household waste.

8. GONAL-f pre-filled pen Treatment Diary

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This Instructions for use was last revised in December 2015