

GONAL-f[®]

PRE-FILLED PEN 300 IU - 450 IU - 900 IU

עט מוכן להזרקה 900 IU - 450 IU - 300 IU

قلم جاهز للحقن 900 IU - 450 IU - 300 IU

Injection instructions

הוראות הזרקה

تعليمات الحقن



MERCK

INJECTION INSTRUCTIONS

GONAL-f® Instructions for Use

1. How to use the GONAL-f pre-filled pen
2. How to use the GONAL-f pre-filled pen Treatment diary
3. Before you start using your GONAL-f pre-filled pen
4. Getting your GONAL-f pre-filled pen ready for injection
5. Setting the dose prescribed by your doctor
6. Injecting the dose
7. After the injection
8. GONAL-f pre-filled pen Treatment diary (see table at the end)

NOTE: Please read these instructions for use before using your GONAL-f pre-filled pen. Be sure to follow the instructions precisely, as it may differ from your past experience.

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

- Do not share the pen with others. 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 the prescribed dose



b. Verify a complete injection



c. Read the dose remaining to be injected with another pen



- Give yourself the injection at the same time each day. For example:
- Your doctor or pharmacist will tell you how many GONAL-f pens you will need to complete your treatment.



English

2. How to use the GONAL-f pre-filled pen Treatment diary

A treatment diary is included on the last page of these instructions for use.

Use the treatment diary to record the amount of IUs injected each time.


- Record the treatment day number (1), date (2) and time (3) of injection
- In the first line of the table the content of the pen is already recorded for you (4). Circle the dose prescribed by the doctor.
- Record your prescribed dose in the "Prescribed Dose" section (5)
- Verify you dialed the right dose before injecting (6)
- After the injection, read the number shown in the **Dose Feedback Window**
- Confirm you received 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 the 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)

NOTE:

Using the treatment diary to record your daily injections allows you to verify every day that you received the full prescribed dose.


Examples of a treatment diary of pens of different dosages:

GONAL-f 300 IU pen


1 Treatment day number	2 Date	3 Time	4 Pen Content (IU) 300 IU	5 Prescribed Dose (IU)	6	7	8
					Dose Feedback Window		
					Amount Set to Inject	 Amount Displayed After Injection	
1	10/06	07:00	300 IU	125	125	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
2	11/06	07:00	175 IU	125	125	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
3	12/06	07:00	50 IU	125	125	<input type="checkbox"/> if "0", injection complete	<input checked="" type="checkbox"/> if not "0", inject this amount...75...using new pen
3	12/06	07:00	300 IU	Not applicable	75	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen

English

GONAL-f 450 IU pen

1 Treatment day number	2 Date	3 Time	4 Pen Content (IU) 450 IU	5 Prescribed Dose (IU)	6	7	8
					Dose Feedback Window		
					Amount Set to Inject	 Amount Displayed After Injection	
1	10/06	07:00	450 IU	175	175	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
2	11/06	07:00	275 IU	175	175	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
3	12/06	07:00	100 IU	175	175	<input type="checkbox"/> if "0", injection complete	<input checked="" type="checkbox"/> if not "0", inject this amount...75...using new pen
3	12/06	07:00	450 IU	Not applicable	75	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen

GONAL-f 900 IU pen

1 Treatment day number	2 Date	3 Time	4 Pen Content (IU) 900 IU	5 Prescribed Dose (IU)	6	7	8
					Dose Feedback Window		
					Amount Set to Inject	 Amount Displayed After Injection	
1	10/06	07:00	900 IU	350	350	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
2	11/06	07:00	550 IU	350	350	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
3	12/06	07:00	200 IU	350	350	<input type="checkbox"/> if "0", injection complete	<input checked="" type="checkbox"/> if not "0", inject this amount..... <u>150</u>using new pen
3	12/06	07:00	900 IU	Not applicable	<u>150</u>	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen

Note: The 300 IU pen maximum dose setting is 300 IU, with a 450 IU pen is 450 IU and with a 900 IU pen is 450 IU.

English

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 in front of you



Below is a diagram of what the pen and its parts look like:





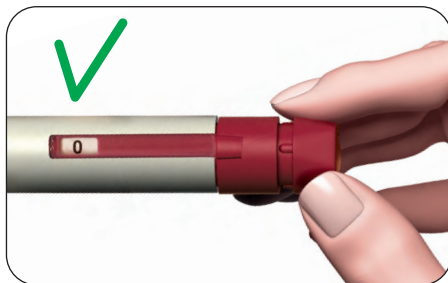
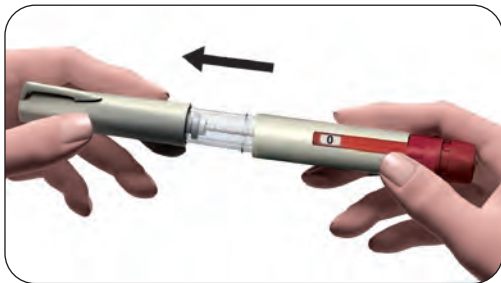
- | | | |
|-------------------------|------------------------------|-------------------------------|
| 1. Dose setting knob | 5. Threaded needle connector | 9. Inner needle shield |
| 2. Dose Feedback window | 6. Pen cap | 10. Outer needle cap |
| 3. Plunger piston | 7. Peel-off seal tab | 11. Alcohol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

English

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.

- Take a new needle – only use the “single-use” needles supplied for a GONAL-f pre-filled pen.
- Hold the outer needle cap firmly.
- Check that the peel-off seal tab on the outer needle cap is not damaged or loose.
- Remove the peel-off seal tab.



CAUTION:

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

4.4. Attach the needle.

- Screw the threaded needle connector of the pen into the outer needle cap until you feel light resistance.



Warning: Do not attach the needle too tightly; it may make it 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.
- Gently remove the green inner needle shield and discard in a disposal collection container.

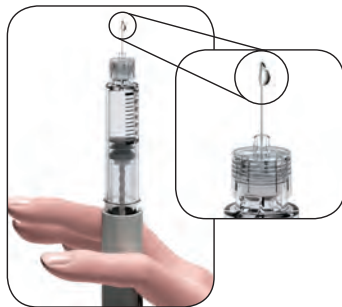


4.5. Look closely at the tip of the needle for a tiny drop of fluid.

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



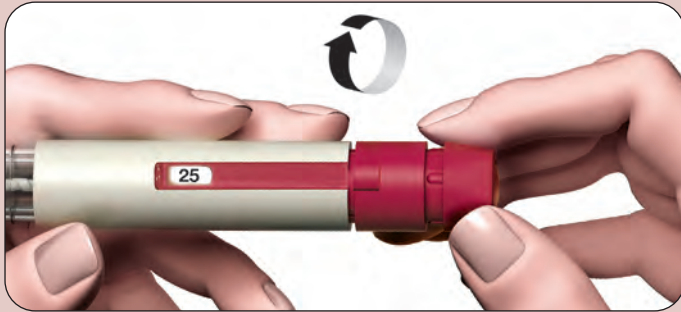
Warning: Checking for a drop is **ONLY** done the **FIRST TIME** you use a new GONAL-f pen to remove air bubbles.



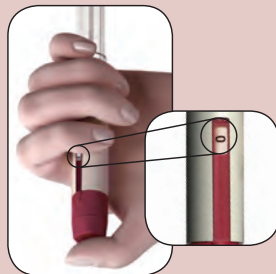
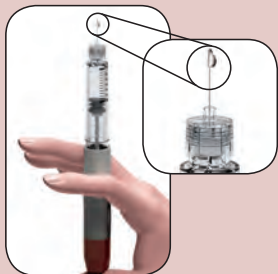
CAUTION:

*If you do not see a tiny drop at or near the needle tip the **first time** you use a new pen, you must perform the following steps.*

If you do not see a tiny drop of fluid at or near the needle 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 setting knob backwards if you turned 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 fluid will appear at the tip of the needle.
5. Verify that the number "0" appears in the Dose Feedback Window.
6. Proceed to **Section 5: Setting the dose prescribed by your doctor**.

5. Setting the dose prescribed by your doctor

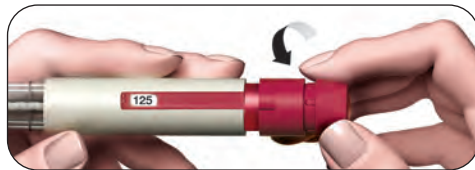
5.1. Your GONAL-f pen can have the following doses:

- A GONAL-f pen containing 300 IU follitropin alfa. The maximum dose setting is 300 IU. The smallest dose setting is 12.5 IU. OR
- A GONAL-f pen containing 450 IU follitropin alfa. The maximum dose setting is 450 IU. The smallest dose setting is 12.5 IU. OR
- A GONAL-f pen containing 900 IU follitropin alfa. The maximum dose setting is 450 IU. The smallest dose setting is 12.5 IU.

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

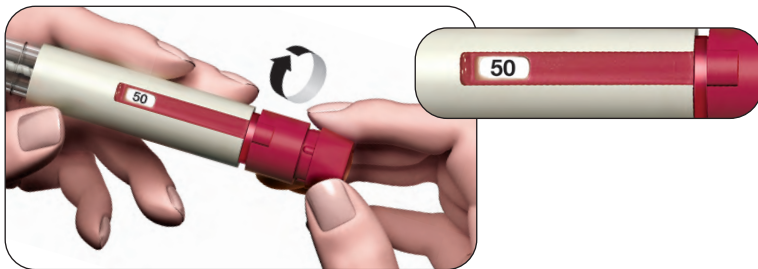


- Turn the dose setting knob **forward** to dial up the desired dose



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

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



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

English

6. Injecting the dose

6.1. Choose the injection area - as your doctor or nurse has explained to you.

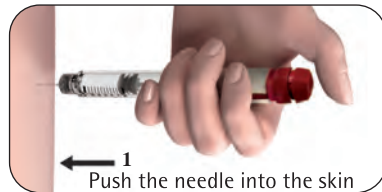
To minimize skin irritation, select a different injection area each day.

6.2. Clean the skin with an alcohol swab.

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

6.4. Inject the dose as you were trained to do by your doctor or nurse.

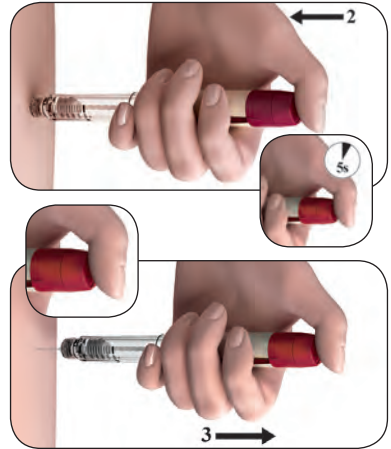
- Slowly push the needle into the skin entirely (1).
- **Press the dose setting knob down as far as it will go** and keep the needle in the skin until the injection is complete.



- Hold the dose setting knob down for a minimum of 5 seconds (s) 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.



English

7. After the injection

7.1. Verify you have given a complete injection.

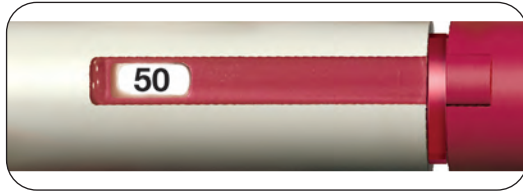
- Check that the Dose Feedback Window shows "0".



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

7.2. Complete a partial injection (only when needed).

- The Dose Feedback Window will display the amount you still need to inject using a new pen.



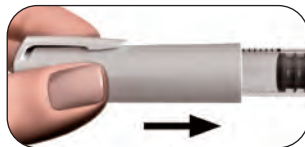
- Repeat Section 3 ("Before you start using your GONAL-f pre-filled pen") and Section 4 ("Getting your GONAL-f pre-filled pen ready for injection") with the new pen.
- Set the dose to the missing amount you recorded in the treatment diary or to the number still displayed in the Dose Feedback Window on 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".
- Grip the outer needle cap and unscrew the needle by **turning anticlockwise**. Dispose of the needle into a sharps disposal container.



- Never reuse the same 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 recapping the pen.


- 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.


English

8. GONAL-f pre-filled pen Treatment diary

1 Treatment day number	2 Date	3 Time	4 Pen Content (IU) 300 IU 450 IU 900 IU	5 Prescribed Dose (IU)	6	7	8
					Dose Feedback Window		
					Amount Set to Inject	 Amount Displayed After Injection	
	/	:	300/450/900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this mount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0",	<input type="checkbox"/> if not "0", inject this

	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen

English

1 Treatment day number	2 Date	3 Time	4 Pen Content (IU) 300 IU 450 IU 900 IU	5 Prescribed Dose (IU)	6	7	8
					Dose Feedback Window		
					Amount Set to Inject	 Amount Displayed After Injection	
	/	:	300/450/900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	.	_____ IU			<input type="checkbox"/> if "0",	<input type="checkbox"/> if not "0", inject this

	/	:	_____ IU			injection complete	amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen
	/	:	_____ IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", inject this amount.....using new pen

Note: The maximum dose you can set with the 300 IU pen is 300 IU, with the 450 IU pen is 450 IU and with the 900 IU pen is 450 IU.

Instructions for use were approved by the Ministry of Health in October 2017