

Instructions for use

GONAL-f PRE-FILLED PEN 900 IU/1.44 mL

Solution for injection in pre-filled pen

Follitropin alfa

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GONAL-f pre-filled pen treatment diary

Important information about the GONAL-f pre-filled pen

- Read the Instructions for Use and the Package Leaflet before using your GONAL-f pre-filled pen.
- Always follow all directions in this Instructions for Use and training provided by your healthcare provider as they may differ from your past experience. This information will allow to prevent incorrect treatment or infection by needle stick or broken glass injury.
- The GONAL-f pre-filled pen is for subcutaneous injection only.
- Only use the GONAL-f pre-filled pen if your healthcare provider trains you on how to use it correctly.
- Your healthcare provider will tell you how many GONAL-f pre-filled pens you need to complete your treatment.
- Give yourself the injection at the same time each day.
- The numbers in the **Dose Feedback Window** represent the number of International Units, or IUs, and show the dose of follitropin alfa. Your healthcare provider will tell you how many IUs of follitropin alfa to inject each day.
- The numbers displayed in the **Dose Feedback Window** help you to:

- a. Dial your prescribed dose (Figure 1).



Fig. 1

- b. Verify a complete injection (Figure 2).



Fig. 2

- c. Read the dose remaining to be injected with a second pen (Figure 3).



Fig. 3

- Remove the needle from the pen immediately after each injection.

Do not reuse needles.

Do not share the pen and/or needles with another person.

Do not use the GONAL-f pre-filled pen if it has been dropped, or the pen is cracked or damaged as this can cause injury.


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 injected. Injecting an incorrect amount of medicine could affect your treatment.

- Record the treatment day number (column 1), date (column 2), time of your injection (column 3), and volume of your pen (column 4).
- Record your prescribed dose (column 5).
- Check you dial the right dose before injecting (column 6).
- After injection, read the number shown in the **Dose Feedback Window**.
- Confirm you receive a complete injection (column 7) or record the number shown in the **Dose Feedback Window** if other than “0” (column 8).
- When needed, inject yourself using a second pen, dialing your remaining dose written in the “Amount to Be Set for a Second Injection” section (column 8).
- Record this remaining dose in the “**Amount Set to Inject**” section (column 6) in the next row.

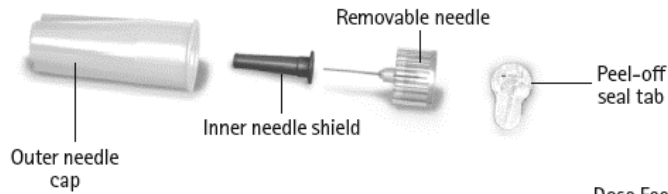
Using your treatment diary to record your daily injection(s) allows you to verify every day that you received the full prescribed dose.

An example of a treatment diary:

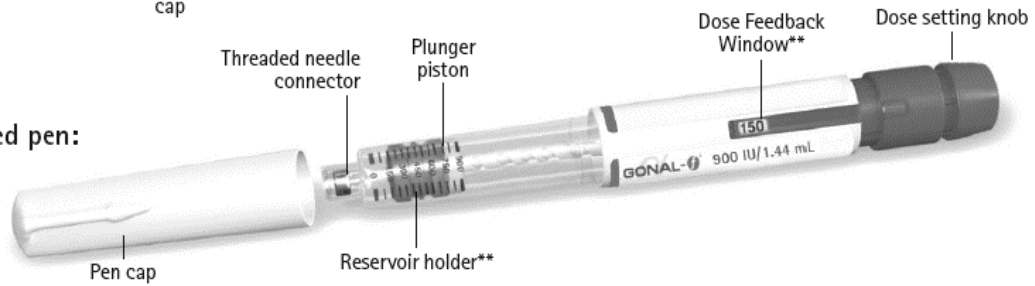
1 Treatment Day Number	2 Date	3 Time	4 Pen Volume <small>900 IU/1.44 mL</small>	5 Prescribed Dose	6 7 8 Dose Feedback Window		
					Amount Set to Inject	Amount to Be Set for a Second Injection	
							
#1	10/06	07:00	900 IU	350	350	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
#2	11/06	07:00	900 IU	350	350	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
#3	12/06/	07:00	900 IU	350	350	<input type="checkbox"/> if "0", injection complete	<input checked="" type="checkbox"/> if not "0", need second injection Inject this amount 150 using new pen
#3	12/06	07:00	900 IU	N/A	150	<input checked="" type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen

Get familiar with your GONAL-f pre-filled pen

Your needle*:



Your pre-filled pen:



*For illustrations purposes only.

**The numbers in the Dose Feedback Window and reservoir holder represent the number of International Units (IU) of medicine.

Step 1 Gather your supplies

- 1.1 Let the pre-filled pen sit at room temperature for at least 30 minutes before use to allow the medicine to reach room temperature.

Do not use a microwave or other heating element to warm up the pen.

- 1.2 Prepare a clean area and a flat surface, such as a table or countertop, in a well-lit area.
- 1.3 You will also need (not included in the pack):

- Alcohol swabs and a sharps container (Figure 4).

- 1.4 Wash your hands with soap and water and dry them well (Figure 5).

- 1.5 Use your hand to remove the GONAL-f pre-filled pen from the pack.

Do not use any tools, using tools might damage the pen.

- 1.6 Check the name on the pre-filled pen says GONAL-f.

- 1.7 Check the expiration date on the pen label (Figure 6).

Do not use the GONAL-f pre-filled pen if the expiration date has passed or if your pre-filled pen does not say GONAL-f.



Fig. 4



Fig. 5

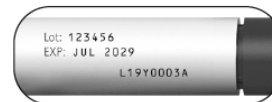


Fig. 6

Step 2 Get ready for injection

- 2.1 Pull-off the pen cap (Figure 7).
- 2.2 Check that medicine is clear, colourless and does not contain particles.

Do not use the pre-filled pen if the medicine is discolored or cloudy, as this can cause an infection.

- 2.3 Check that the Dose Feedback Window is set to “0” (Figure 8).

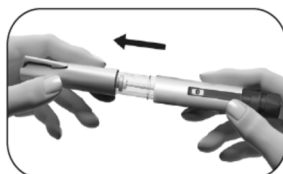


Fig. 7

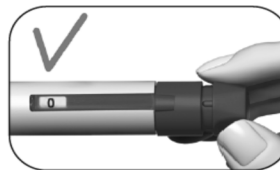


Fig. 8

Choose your injection site:

- 2.4 Your healthcare provider should show you the injection sites to use around your stomach area (Figure 9). To minimise skin irritation, select a different injection site each day.

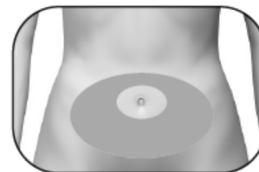


Fig. 9

- 2.5 Clean the skin at the injection site by wiping with an alcohol swab.

Do not touch or cover the cleaned skin.

Step 3 Attach your needle

Important: Always make sure to use a new needle for each injection. Re-using needles can cause infection.

- 3.1 Get a new needle. Only use the “single-use” needles supplied.
- 3.2 Check that the outer needle cap is not damaged.
- 3.3 Hold the outer needle cap firmly.
- 3.4 Check that the peel-off seal on the outer needle cap is not damaged or loose, and that expiration date has not passed (Figure 10).
- 3.5 Remove the peel-off seal (Figure 11).



Fig. 10

Do not use the needle if it is damaged, expired or if the outer needle cap or the peel-off seal is damaged or loose. Using expired needles or needles with damaged peel-off seal or outer needle cap can lead to infection. Throw it away in a sharps container and get a new needle.



Fig. 11

- 3.6 Screw the outer needle cap onto the threaded tip of the GONAL-f pre-filled pen until you feel a light resistance (Figure 12).

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

- 3.7 Remove the outer needle cap by pulling it gently (Figure 13).

- 3.8 Put it aside for later use (Figure 14).

Do not discard the outer needle cap, as it will prevent needle stick injury and infection when detaching the needle from the pre-filled pen.

- 3.9 Hold the GONAL-f pre-filled pen with the needle pointing upward (Figure 15).
- 3.10 Carefully remove and discard the green inner needle shield (Figure 16).

Do not recap the needle with the green inner needle shield, as it can lead to needle stick injury and infection.

3.11 Look closely at the tip of the needle for tiny droplet(s) of liquid.



Fig. 12

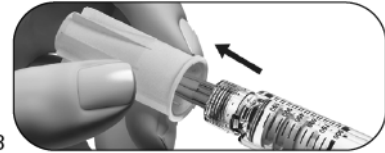


Fig. 13

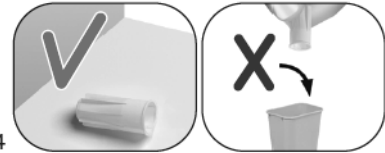


Fig. 14

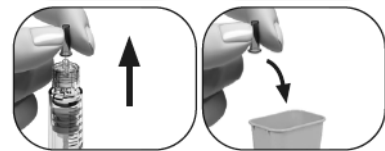


Fig. 15

Fig. 16

If	Then
Using a new pen	<p>Check for a droplet of liquid at the tip of the needle (Figure 17).</p> <ul style="list-style-type: none"> • If you see a tiny droplet of liquid, proceed to Step 4 Dial your dose. • If you do not see a tiny droplet at or near the needle tip, you must perform the steps on the next page to remove air in the system.
Reusing a pen	<p>It is NOT required to check for a droplet of liquid. Proceed directly to Step 4 Dial your dose.</p>

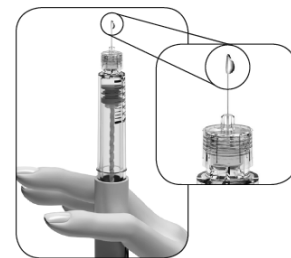


Fig. 17

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

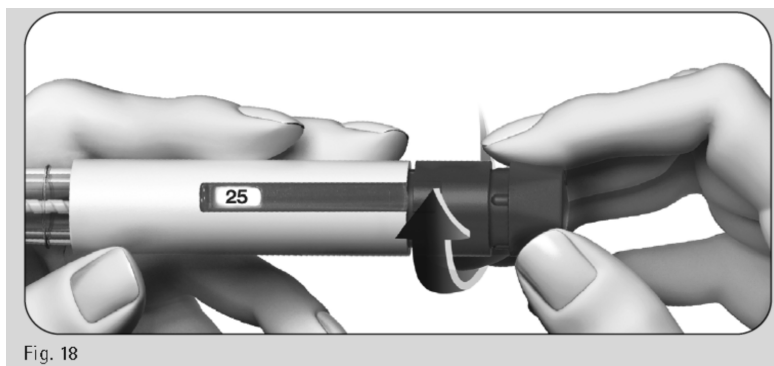
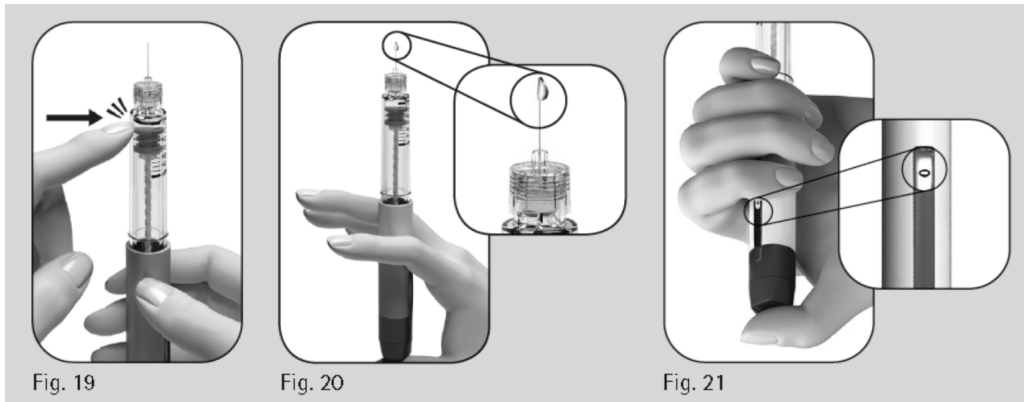


Fig. 18

1. Gently turn the dose setting knob forward until it reads **“25”** in the **Dose Feedback Window** (Figure 18).
 - You can turn the dose knob backward if you turn it past **“25”**.



2. Hold the pen with the needle pointing upward.
3. Tap the reservoir holder gently (Figure 19).
4. Press the dose setting knob **as far as it will go**. A tiny droplet of liquid will appear at the tip of the needle (Figure 20).
5. Check that the **Dose Feedback Window** reads “0” (Figure 21).
6. Proceed to **Step 4 Dial your dose**.

If a tiny droplet of liquid does not appear, contact your healthcare provider.

Step 4 Dial your dose

Note: The pen contains 900 IU follitropin alfa. The 900 IU pen maximum single-dose setting is 450 IU. The smallest single-dose setting is 12.5 IU and the dose can be increased in increments of 12.5 IU.

- 4.1 Turn the dose setting knob until your intended dose shows in the Dose Feedback Window.
 - Example: If your intended dose is “150” IU, confirm that the Dose Feedback Window reads “150” (Figure 22). Injecting an incorrect amount of medicine could affect your treatment.

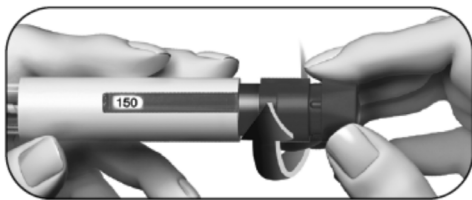


Fig. 22

- Turn the dose setting knob **forward** to dial up (Figure 22).

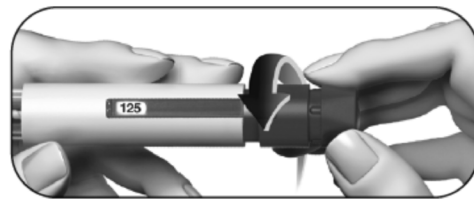


Fig. 23

- You can turn the dose setting knob **backwards** if you turn it past your intended dose (Figure 23).

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

Step 5 Inject your dose

Important: Inject the dose as you were trained to do by your healthcare provider.

5.1 Slowly push the needle into the skin entirely (Figure 24).

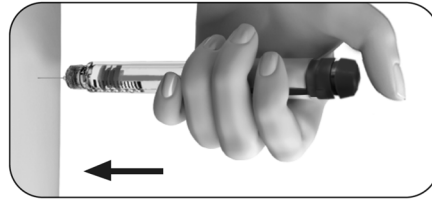


Fig. 24

5.2 Place your thumb in the middle of the dose setting knob. **Slowly press the dose knob down as far as it will go** and hold it to complete the full injection (Figure 25).

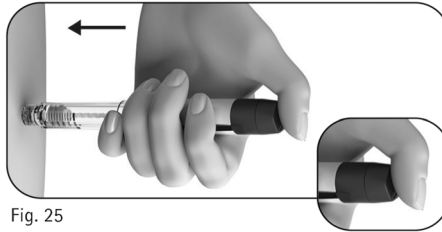


Fig. 25

Note: The larger the dose, the longer it will take to inject.

5.3 Hold the dose knob down for a minimum of 5 seconds before you remove the needle from your skin (Figure 26).



Fig. 26

- 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** (Figure 27).
- When the needle is out of the skin, release the dose setting knob.

Do not release the dose knob until you remove the needle from the skin.

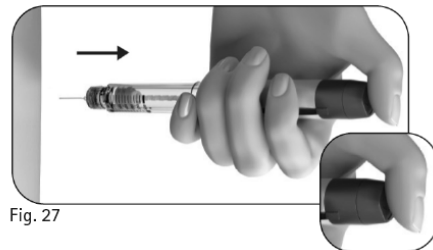


Fig. 27

Step 6 Remove the needle after each injection

6.1 Place the outer needle cap on a flat surface.

6.2 Hold the GONAL-f pre-filled pen firmly with one hand and slip the needle into the outer needle cap (Figure 28).

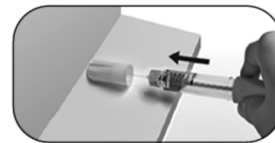


Fig. 28

6.3 Continue by pushing the capped needle against a firm surface until you hear a “click” (Figure 29).



Fig. 29

6.4 Grip the outer needle cap and unscrew the needle by turning it in the opposite direction (Figure 30).



Fig. 30

6.5 Dispose of the used needle safely in a sharps container (Figure 31). Handle the needle with care to avoid getting injured by the needle.



Fig. 31

Do not reuse or share any used needle.

Step 7 After the injection

7.1 Check you have given a complete injection:

- Check that the Dose Feedback Window shows “0” (Figure 32).

If the Dose Feedback Window shows “0”, you have completed your dose.

If the Dose Feedback Window shows a number **higher than “0”**, the GONAL-f pre-filled pen is empty. You have not received your full prescribed dose and you must perform step 7.2 below.

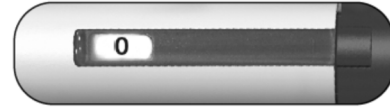


Fig. 32

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. In the example shown, the missing amount is “50” IU (Figure 33).

To complete the dose with a second pen, repeat Steps 1 through 8.



Fig. 33

Step 8 Store the GONAL-f pre-filled pen

8.1 Put the pen cap back onto the pen to avoid infection (Figure 34).

8.2 Store the pen with the cap on it in a safe place and as indicated in the Package Leaflet.

8.3 When the pen is empty, ask your healthcare provider how to dispose of it.

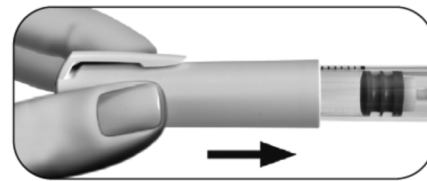



Fig. 34

Do not store the pen with the needle still attached, as this may cause infection.

Do not reuse the GONAL-f pre-filled pen if it has been dropped, or the pen is cracked or damaged as this can cause injury.

Contact your healthcare provider if you have questions.

GONAL-f pre-filled pen treatment diary

1	2	3	4	5	6	7	8
Treatment Day Number	Date	Time	Pen Volume	Prescribed Dose	Dose Feedback Window		
			900 IU/1.44 mL		Amount Set to Inject		Amount to Be Set for a Second Injection

	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen -
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen
	/	:	900 IU			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection Inject this amountusing new pen

This Instructions for Use has been last revised in: 11/2023.