Instructions for use

GONAL-f ®

pre-filled pen
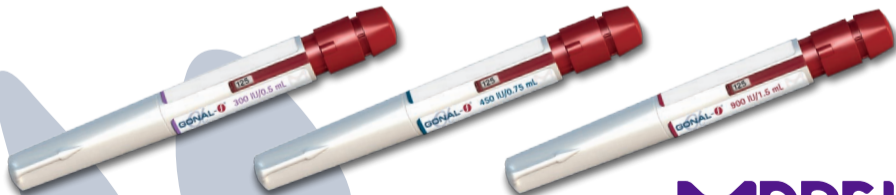
300 IU/0.5 mL

תעלימات الاستعمال

جونال - إف ®

قلم جاهز للحقن

450 IU/0.75 mL

Follitropin Alfa

הוראות שימוש

גונאל-אף ®

עט מוכן להזרקה

900 IU/1.5 mL

Merck

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Important information about the Gonal-f pre-filled pen

- Read the Instructions for use and the Patient leaflet before using Gonal-f.

- Always follow these 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 due to needle stick or broken glass injury.

- The Gonal-f pen is intended for subcutaneous injection only.

- Only use the Gonal-f pen if your healthcare provider has trained you on how to use it correctly.

- Your healthcare provider will tell you how many Gonal-f pens you need to complete your treatment.

- Inject the medicine at the same time each day.

- The numbers displayed in the **Dose feedback window** represent the number of International Units (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. Set your prescribed dose (Figure 1)
  b. Verify a complete injection (Figure 2)
  c. Read the dose remaining for injection with an additional pen (Figure 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 pen if it has been dropped, cracked or damaged, as this may cause injury.
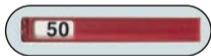

Figure 1

Figure 2

Figure 3

ENGLISH

How to use your Gonal-f pre-filled pen treatment diary

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

Use the treatment diary to record the amount injected. Injecting an incorrect amount of medicine may affect your treatment.

- Record the treatment day number (column 1), date (column 2), time of injection (column 3), and volume of the pen (column 4).
- Record your prescribed dose (column 5).
- Check that you set the right dose before injecting (column 6).
- After injection, read the number shown in the **Dose feedback window**.
- Verify that you have received a complete injection (column 7) or record the number shown in the **Dose feedback window** if other than "0" (column 8).
- If needed, inject yourself using an additional pen, setting your remaining dose written in the "Amount to be set for a second injection" section (column 8).
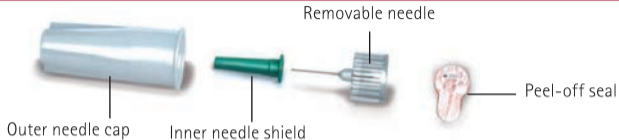- Record this remaining dose in the **"Amount set to inject"** section (column 6) in the next row.

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

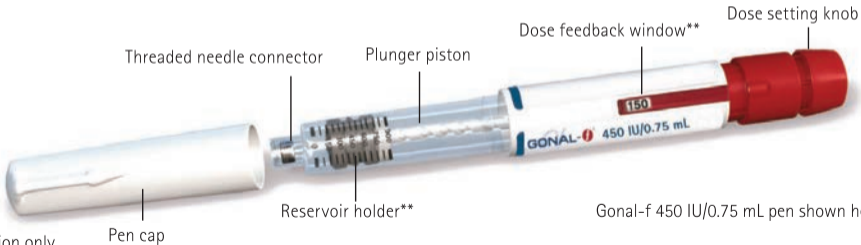An example of a treatment diary using a **450 IU/0.75 mL** pen:

1 Treatment day number	2 Date	3 Time of injection	4 Pen volume (IU) 300 IU/0.5 mL 450 IU/0.75 mL 900 IU/1.5 mL	5 Prescribed dose	6 Amount set to inject	7 Dose feedback window 	8 Amount to be set for a second injection
#1	10/06	07:00	450 IU	175	175	☑ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
#2	11/06	07:00	450 IU	175	175	☑ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
#3	12/06	07:00	450 IU	175	175	☐ if "0", injection complete	☑ if not "0", inject this amount 75 using a new pen
#3	12/06	07:00	450 IU	N/A	75	☑ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen

Get familiar with the Gonal-f pre-filled pen

The needle*:

Removable needle

Outer needle cap

Inner needle shield

Peel-off seal

The pen:

Threaded needle connector

Plunger piston

Dose feedback window**

Dose setting knob

GONAL-f 450 IU/0.75 mL

150

Reservoir holder**

Pen cap

Gonal-f 450 IU/0.75 mL pen shown here

* For illustration only

** The numbers in the **Dose feedback window** and reservoir holder represent the number of International Units of medicine.

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Step ❶ Prepare the supplies

1.1. Let the pen stay 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 and 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 pen from the pack.

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

1.6. Check the name on the pen: "Gonal-f".

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

Do not use the Gonal-f pen if the expiration date has passed or if "Gonal-f" is not written on it.

Figure 4

Figure 5

Figure 6

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Step ❷ Get ready for injection

2.1. Pull-off the pen cap (Figure 7).

2.2. Check that the medicine is clear, colourless and does not contain particles.

Do not use the pen if the medicine is discoloured or cloudy, as this may cause infection.

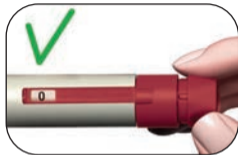**2.3.** Check that the Dose feedback window is set to "0" (Figure 8).

Figure 7

Figure 8

Choose your injection site:

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

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

Do not touch or cover the cleaned skin.

Figure 9

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Step ❸ Attach the needle

Important: Always make sure to use a new needle for each injection. Re-using needles may 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 the expiration date has not passed (Figure 10).

3.5. Remove the seal (Figure 11).

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

Figure 10

Figure 11

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3.6. Screw the outer needle cap onto the threaded tip of the Gonal-f 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 pen.

3.9. Hold the Gonal-f 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 this may lead to needle stick injury and infection.

Figure 12

Figure 13

Figure 14

Figure 15   Figure 16

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3.11. Look closely at the tip of the needle for tiny droplets of liquid.

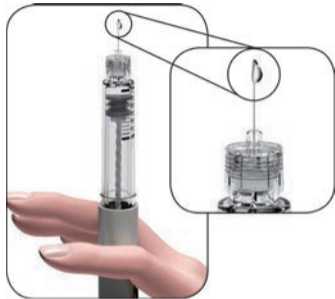| If	Then
Using a new pen	Check for a droplet of liquid at the tip of the needle (Figure 17). • If you see a tiny droplet of liquid, proceed to **Step 4 Set your dose**. • If you do not see a tiny droplet at or near the needle tip, you must perform the steps **on the next page** to remove air from the system.
Reusing a pen	It is NOT required to check for a droplet of liquid. Proceed directly to **Step 4 Set your dose**.

Figure 17

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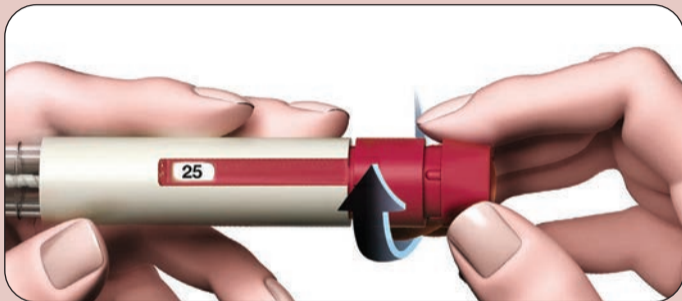

Figure 18

1. Gently turn the dose setting knob forward until the **Dose feedback window shows "25"** (Figure 18).
   • You can turn the dose setting knob backward if you turn it past "25".
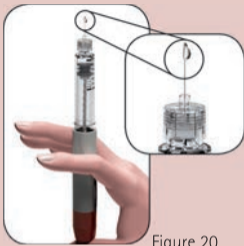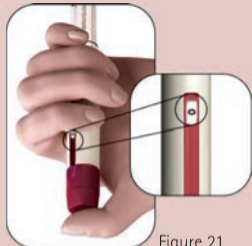
Figure 19

Figure 20

Figure 21

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** shows "0" (Figure 21).
6. Proceed to **Step 4 Set your dose**.

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

Step ❹ Set your dose

Note:

The pen comes in three different multi-dose presentations:

- Gonal-f pen containing 300 IU of follitropin alfa.
  The maximal dose you can set is 300 IU.

- Gonal-f pen containing 450 IU of follitropin alfa.
  The maximal dose you can set is 450 IU.

- Gonal-f pen containing 900 IU of follitropin alfa.
  The maximal dose you can set is 450 IU.

- The smallest dose you can set is 12.5 IU, the dose setting knob can be turned in increments of 12.5 IU.

4.1. Turn the dose setting knob until your intended dose is displayed in the Dose feedback window.

- Example: If your intended dose is "150" IU, verify that the Dose feedback window shows "150" (Figure 22). Injecting an incorrect amount of medicine could affect your treatment.
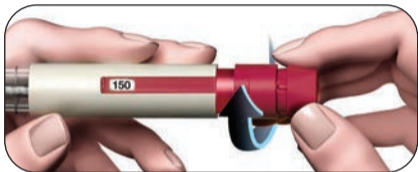

Figure 22

Figure 23

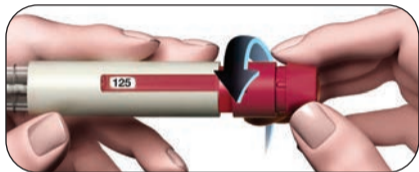- Turn the dose setting knob **forward** (Figure 22).

- 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 ➎ Inject your dose

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

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

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

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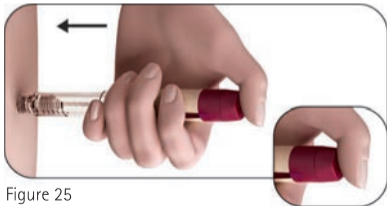

Figure 24

Figure 25

5.3. Hold the dose setting knob pressed down for at least 5 seconds (5s) before you remove the needle from the skin (Figure 26).

- The dose number shown in the **Dose feedback window** will turn back to "0".

Figure 26

- 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.

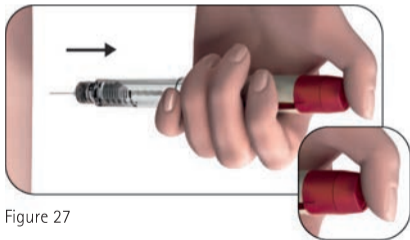**Do not** release the dose setting knob until you remove the needle from the skin.

Figure 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 pen firmly with one hand and slip the needle into the outer needle cap (Figure 28).

Figure 28

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

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

Figure 29

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.

Do not reuse or share any used needle.

Figure 30

Figure 31

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Step ❼ After the injection

7.1. Check that you have received 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 pen is empty. You have not received your full prescribed dose and you must perform step 7.2 below.

Figure 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 1-8.

Figure 33

Step ❽ 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 in its original packaging in a safe place and as indicated in the Patient leaflet.

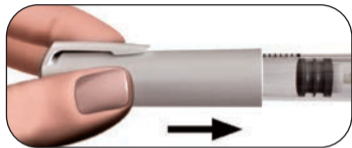**8.3.** When the pen is empty, ask your healthcare provider how to dispose of it.

Figure 34

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

Do not reuse the Gonal-f pen if it has been dropped, cracked or damaged, as this may cause injury.

Contact your healthcare provider if you have questions.

Gonal-f pre-filled pen treatment diary

1 Treatment day number	2 Date	3 Time of injection	4 Pen volume (IU) 300 IU/0.5 mL 450 IU/0.75 mL 900 IU/1.5 mL	5 Prescribed dose	6 Amount set to inject	7 Dose feedback window 0	8 Amount to be set for a second injection
	/	:				☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:				☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:				☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:				☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:				☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen

	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen
	/	:					☐ if "0", injection complete	☐ if not "0", inject this amount .... using a new pen

The Instructions for injection were revised in November 2022 according to MOH guidelines.