



Instructions for use

Pergoveris®
Pre-filled pen

(300 IU + 150 IU)/0.48 mL

تعليمات إستعمال

پرچو قريس®
قلم جاهز للحقن

(450 IU + 225 IU)/0.72 mL

הוראות שימוש

פרגובריס®
עט מוכן להזרקה

(900 IU + 450 IU)/1.44 mL



MERCK

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Warning: Please read these instructions for use before using the Pergoveris® pre-filled pen. Follow the instructions exactly, as they may differ from your past experience.

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1. Important Information regarding the Pergoveris® pre-filled pen

- The Pergoveris® pre-filled pen is intended for subcutaneous injection only.
- Only use the Pergoveris® pre-filled pen if your healthcare provider instructed you how to use it properly.



Warning: Do not reuse needles. Remove the needle immediately after each injection. **Do not share** the pen and/or needles with another person as doing so can cause an infection.

- The pen comes in 3 different multi-dose presentations:

(300 IU + 150 IU)/0.48 mL

- Contains 0.48 mL of Pergoveris® solution
- Contains 300 IU follitropin alfa and 150 IU lutropin alfa

(450 IU + 225 IU)/0.72 mL

- Contains 0.72 mL of Pergoveris® solution
- Contains 450 IU follitropin alfa and 225 IU lutropin alfa

(900 IU + 450 IU)/1.44 mL

- Contains 1.44 mL of Pergoveris® solution
- Contains 900 IU follitropin alfa and 450 IU lutropin alfa



Warning: Refer to the Package Leaflet for more information on the recommended dose regimen and always follow the dosage recommended by your doctor.

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- The numbers in the **Dose Feedback Window** represent the number of International Units, or IUs, and show the dose of follitropin alfa. Your doctor will instruct you on 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.

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. For example:



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

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2. How to use the Pergoveris® pre-filled pen treatment diary

A treatment diary is included on the last page. Use the treatment diary to record the amount injected.

- Record the treatment day number (column 1), date (column 2), time of injection (column 3), and pen volume (column 4)
- Record your prescribed dose (column 5)
- Verify that you set the right dose before injecting (column 6)
- After injection, read the number shown in the **Dose Feedback Window**
- Confirm you received 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 another pen, setting the 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 in the next row (column 6)

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

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3. Gathering the necessary supplies

- 3.1. Wash your hands with soap and water (Fig. 1)
- 3.2. Find a **clean and flat surface**, such as a table or countertop, in a well-lit area
- 3.3. Select a Pergoveris® pre-filled pen
- 3.4. Verify you have selected the prescribed pen

- 3.5. Check the **expiration date** indicated on the pen label (Fig. 2)
- 3.6. You will also need:
 - Needles (included in the pack)
 - Alcohol swabs (not included in the pack)
 - A sharps disposal bin (not included in the pack)

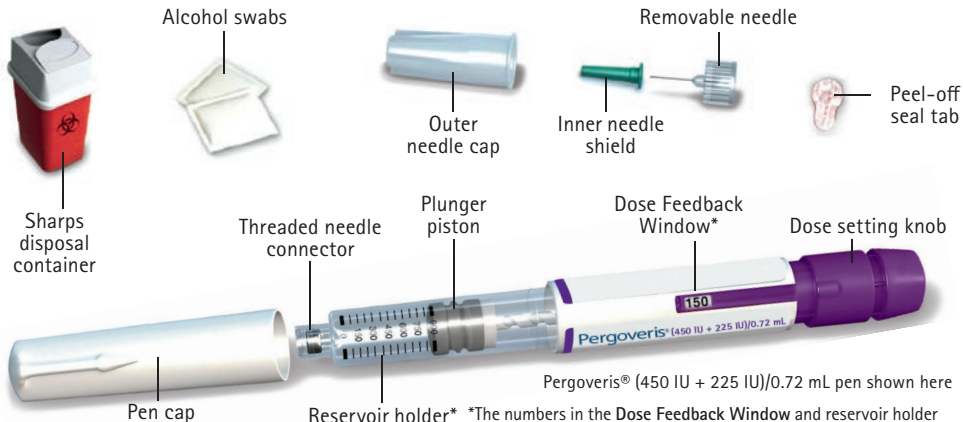


Fig. 1



Fig. 2

4. Getting familiar with the parts of the Pergoveris® pre-filled pen



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

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5. Getting the Pergoveris® pre-filled pen ready for injection

5.1. Take off the pen cap.

5.2. Verify that the Dose Feedback Window is set to "0."



5.3. Prepare your needle.

- Take a new needle—only use the "single-use" needles provided for Pergoveris® pre-filled pen.
- Hold the outer needle cap firmly.
- Check that the peel-off seal on the outer needle cap is not damaged or loose (Fig. 3).
- Remove the peel-off seal (Fig. 4).



Caution:

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



Fig. 3



Fig. 4

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5.4. Attach the needle

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

! **Caution:** Do not attach the needle too tightly; this may make it difficult to remove after the injection.

- Gently remove the outer needle cap by pulling it.
- Put it aside for later use. **DO NOT** discard it.
- Hold the Pergoveris® pre-filled pen with the needle pointing upward.
- Carefully remove and discard the green inner shield.

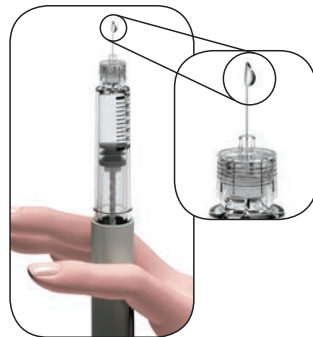
! **Warning:** Do not recap the needle with the green inner shield as this may lead to needlestick.



5.5. Check for a droplet of liquid at the tip of the needle

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

IF	THEN
Using a new pen	Check for a droplet of liquid at the tip of the needle. <ul style="list-style-type: none">• If you see a droplet, proceed to Section 6: Setting the dose prescribed by your doctor.• If you do not see a droplet, follow the instructions on the following page.
Reusing a pen	There is no need to check for a droplet of liquid. Proceed directly to Section 6: Setting the dose prescribed by your doctor.



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

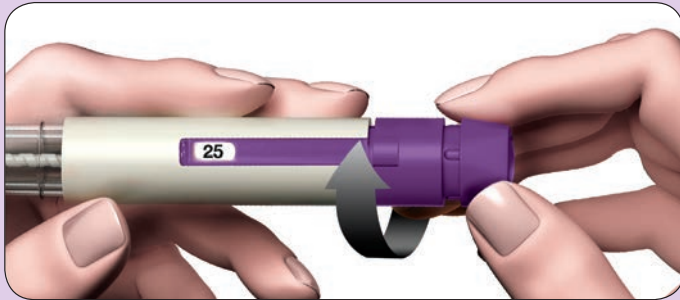


Fig. 5

1. Gently turn the dose setting knob clockwise until it **reads 25** in the **Dose Feedback Window**. You can turn the dose setting knob backward if you turned it past 25 (Fig. 5).



Fig. 6

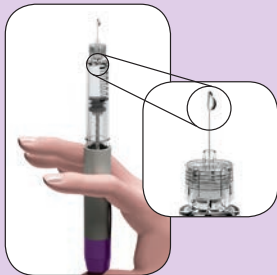


Fig. 7

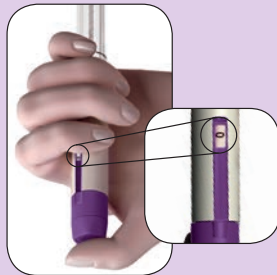


Fig. 8

2. Hold the pen with the needle pointing upward.
3. Tap the reservoir holder gently (Fig. 6).
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 (Fig. 7).
5. Verify that the number "0" appears in the **Dose Feedback Window** (Fig. 8).
6. Proceed to **Section 6: Setting the dose prescribed by your doctor**.

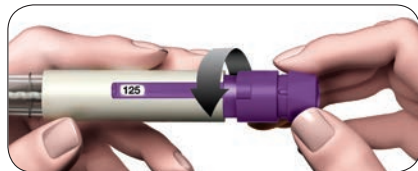
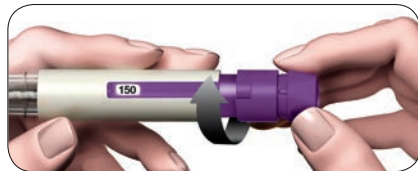
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6. Setting the dose prescribed by your doctor

6.1. Turn the dose setting knob until the desired dose appears in the Dose Feedback Window.

- Turn the dose setting knob **forward** to reach the dose that was prescribed by your doctor
- If needed, turn the dose setting knob **backward** to correct the dose



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

7. Injecting the dose

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

7.2. Clean the skin with an alcohol swab.

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



Injection area

7.4. Inject the dose as you were instructed to by your doctor or nurse.

- Slowly push the needle into the skin entirely (Fig. 9).
- **Slowly press the dose setting knob down as far as it will go** and hold it to complete the full injection.

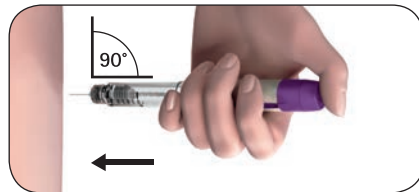


Fig. 9

- Hold the dose setting knob down for at least 5 seconds (s) to ensure that you injected the full dose (Fig. 10).
- The dose number shown in the **Dose Feedback Window** will turn back to 0.

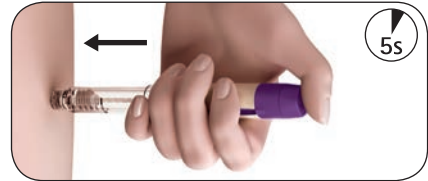


Fig. 10

- After at least 5 seconds, **while continuing to press on the dose setting knob**, pull the needle out of the skin (Fig. 11).
- When the needle is out of the skin, release the dose setting knob.

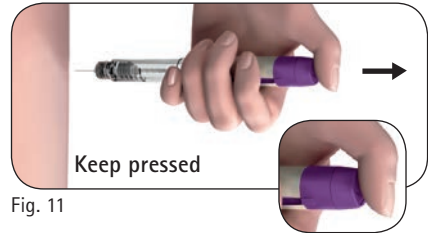


Fig. 11



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



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

8. After the injection

8.1. Verify you have given a complete injection.

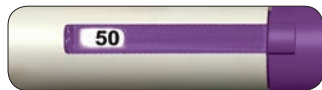
- Check that the Dose Feedback Window shows "0."



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

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

- The **Dose Feedback Window** will indicate the dose that should be completed, which you need to inject with a new pen.
- Repeat Section 4 (**Getting familiar with the Pergoveris® pre-filled pen**) and Section 5 (**Getting the Pergoveris® pre-filled pen ready for injection**) with a 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 the previous pen, and inject.

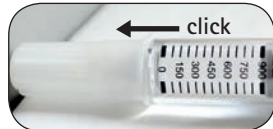


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8.3. Removing the needle after each injection.

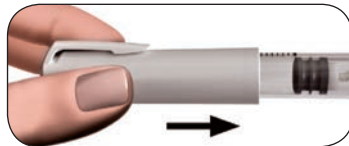
- Place the outer needle cap on a flat surface
- Hold the Pergoveris® pre-filled pen firmly with one hand, and slip the needle into the outer needle cap.
- Continue by pushing the capped needle against a firm surface until you hear a "click".
- Grip the outer needle cap and unscrew the needle by **turning anti-clockwise**. Dispose of the needle safely.
- Recap the pen.




 **Warning:** Never reuse any used needle. Never share needles.

8.4. Storing the Pergoveris® pre-filled pen.


 **Caution:** Never store the pen with the needle still attached. Always remove the needle from the Pergoveris® pre-filled pen before replacing the pen cap.



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

 **Warning:** Do not dispose of medicines via wastewater or household waste.

9. Pergoveris® pre-filled pen treatment diary

1 Treatment Day Number	2 Date	3 Time	4 Pen Volume (300 IU + 150 IU)/0.48 mL (450 IU + 225 IU)/0.72 mL (900 IU + 450 IU)/1.44 mL	5 Prescribed Dose	6	7	8
					Dose Feedback Window		
					Amount Set to Inject	 Amount to Be Set for a Second Injection	
	/	:			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection. Inject this amountusing new pen	
	/	:			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection. Inject this amountusing new pen	
	/	:			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection. Inject this amountusing new pen	
	/	:			<input type="checkbox"/> if "0", injection complete	<input type="checkbox"/> if not "0", need second injection. Inject this amountusing new pen	
					<input type="checkbox"/> if "0".	<input type="checkbox"/> if not "0". need second injection.	

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

The instructions for use were approved by the Ministry of Health on June 2018.

Pergoveris®
Pre-filled pen

پرچو فریس®
قلم جاهز للحقن

פרגובריס®
עט מוכן להזרקה

(300 IU + 150 IU)/0.48 mL (450 IU + 225 IU)/0.72 mL (900 IU + 450 IU)/1.44 mL

Solution for injection in pre-filled pen
תמיסה להזרקה בעט מוכן להזרקה
מחול לחقن ضمن قلم جاهز للحقن



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