PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

PERGOVERIS® Pre-filled pen
Solution for Subcutaneous Injection

Active ingredients:
Follitropin Alfa (r-hFSH)
Lutropin Alfa (r-hLH)

Provided in three volumes:
Pergoveris (300 IU* r-hFSH + 150 IU r-hLH)/0.48 mL
Pergoveris (450 IU r-hFSH + 225 IU r-hLH)/0.72 mL
Pergoveris (900 IU r-hFSH + 450 IU r-hLH)/1.44 mL
(*IU – international units)

Inactive and allergenic ingredients in the preparation – see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may need to read it again.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
The medicine is not intended for girls and adolescent girls below the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR

The medicine is intended for stimulation of follicles and their maturation in the ovaries in adult women with severe gonadotropin hormone deficiency (FSH and LH).
In clinical trials, patients were defined by levels of LH (the luteinizing hormone) in the blood, below 1.2 international units per liter.

Therapeutic group: Gonadotropin hormones that are involved in regulating the reproductive system.

The medicine contains 2 active ingredients called Follitropin Alfa and Lutropin Alfa. Both ingredients belong to a group of hormones called gonadotropins that are involved in regulation of the reproductive system.

The active ingredients in the medicine are copies of the natural hormones, FSH and LH in the body:
FSH, follicle stimulating hormone - stimulates maturation of eggs.
LH, luteinizing hormone - stimulates release of the eggs.

The medicine allows women with low levels of FSH and LH to develop a follicle. The injection of another hormone - human chorionic gonadotropin (hCG) - leads to the release of the egg from the follicle.
This process helps to achieve pregnancy.

2. BEFORE USING THE MEDICINE

You and your partner to the fertility process must be examined by a doctor specializing in fertility problems before commencing treatment.

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients (FSH and/or LH) or to any of the additional ingredients contained in the medicine (for a list of the inactive ingredients, see section 6).
- you are suffering from a brain tumor (in the hypothalamus or in the pituitary gland [hypophysis]).
- you are suffering from enlarged ovaries or sacs of fluid within the ovaries (ovarian cysts) of unknown origin.
- you are suffering from unexplained vaginal bleeding.
- you have ovarian, uterine or breast cancer.
- you are suffering from a condition that makes normal pregnancy impossible, e.g., early menopause, sex organ defect (malformation) or a benign uterine tumor.

Do not use the medicine if any of the above conditions apply to you. If you are unsure, consult a doctor, pharmacist or nurse before using the medicine.

Special warnings regarding use of the medicine
Talk to the doctor, pharmacist or nurse before using Pergoveris.

Porphyria
Talk to your doctor before commencing treatment if you or any of your family members have porphyria (a hereditary disease in which there is no ability to break down porphyrins).

Tell your doctor immediately if:
- Your skin becomes fragile and easily blistered, especially after frequent exposure to sunlight.
- You have stomach, arm or leg pain.

In these cases, the doctor may recommend stopping treatment.

Ovarian hyperstimulation syndrome (OHSS)
This medicine stimulates the ovaries and increases the risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). In this condition, your follicles develop too much and become large cysts. If you are suffering from lower abdominal pains, rapid weight gain, nausea, vomiting or if you have breathing difficulties, refer to the doctor immediately. Your doctor might instruct you to stop using this medicine (see section 4, under "Most serious side effects").

In case you are not ovulating and you adhere to the recommended treatment dose and schedule of administration, the risk of severe OHSS is less likely. Pergoveris treatment seldom causes severe OHSS. The risk of onset of this syndrome increases when using a medicine for final follicular maturation (which contains human chorionic gonadotropin - hCG) - see section 3 under “Dosage". If you are developing OHSS, your doctor may not treat you with hCG in this treatment cycle and will ask you not to have sex or will ask you to use a barrier contraceptive method for at least 4 days.

Your doctor will carefully monitor the ovarian response, based on ultrasound and blood tests (estradiol levels) before and during the treatment cycle.

Multiple pregnancy
When using Pergoveris, there is a higher risk of pregnancy with more than one fetus ("multiple pregnancy", mostly twins), compared to a pregnancy resulting from natural conception. Multiple pregnancy may lead to medical complications for you and your babies. You can reduce the risk of multiple pregnancy by using the right dose of Pergoveris and by administration at the right times.
To minimize the risk of multiple pregnancy, ultrasound scans as well as blood tests are recommended.

Miscarriage
When undergoing stimulation of the ovaries to produce eggs, the risk of miscarriage is higher than in the average population.

Ectopic pregnancy
Women who have a history of blocked or damaged fallopian tubes (tubal disease) are at risk of pregnancy in which the fetus implants outside the womb (ectopic pregnancy), in both spontaneous pregnancy and pregnancy following fertility treatments.

Blood clotting problems (thromboembolic events: thromboembolism)
Consult the doctor before using the medicine if you or a member of your family have ever had blood clots in the leg or in the lung, or a heart attack or stroke. You may be at a higher risk of serious blood clots or of worsening of existing clots during treatment with Pergoveris.

Tumors of sex organs
There have been reports of tumors in the ovaries and other sex organs, both benign and malignant, in women who have undergone multiple regimens for infertility treatment.

Allergic reactions
There have been isolated reports of non-serious allergic reactions to Pergoveris. If you have ever had this effect with a similar medicine, inform the doctor before using Pergoveris.

Girls and adolescent girls
Pergoveris is not intended for use in girls and adolescent girls below the age of 18.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not administer Pergoveris with other medical preparations mixed in the same injection.
Pergoveris can be used with a follitropin alfa (FSH) preparation, as separate injections, if prescribed for you by the doctor.

Pregnancy and breastfeeding
Do not use Pergoveris if you are pregnant or breastfeeding.

Driving and operating machinery
This medicine is not expected to affect your ability to drive or operate dangerous machines.

Important information about some of the ingredients in this medicine
Pergoveris contains less than 1 mmol (23 mg) sodium per dose – considered "sodium-free".

Pergoveris (300 IU + 150 IU)/0.48 mL contains 0.176 mg sodium.
Pergoveris (450 IU + 225 IU)/0.72 mL contains 0.263 mg sodium.
Pergoveris (900 IU + 450 IU)/1.44 mL contains 0.527 mg sodium.

3. HOW TO USE THE MEDICINE

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about your dose or about how to take this medicine.

Using the medicine
- Pergoveris is intended to be given by injection under the skin. In order to reduce skin irritation, select a different injection site each day.
- The doctor or nurse will show you how to use the Pergoveris pre-filled pen to inject the medicine.
- Once they confirm that you are able to administer the medicine safely, you can then prepare and inject the medicine yourself at home.
- When you self-inject, carefully read and follow the "Instructions for use" booklet attached to the package.

Dosage
The dosage and treatment regimen will be determined by the doctor only.

A treatment regimen commences with the recommended dosage of Pergoveris containing 150 IU of follitropin alfa and 75 IU of lutropin alfa every day.
- According to your response, your doctor may decide to add a dose of a follitropin alfa preparation every day in addition to your Pergoveris injection. In this case, the follitropin alfa dosage is usually increased every 7 or every 14 days by 37.5-75 IU.
- Treatment is continued until the desired response is achieved. This is when you have developed a suitable follicle, as confirmed by ultrasound scans and blood tests.
- This may take up to 5 weeks.

When the desired response is achieved, you will be given a single injection of human chorionic gonadotropin (hCG) 24-48 hours after the last Pergoveris injection. It is recommended to have sex on the day of the hCG injection and on the following day. Alternatively, intrauterine insemination (IUI) can be performed or assistive reproductive technologies (ART) used.

If your body responds too strongly, the treatment will be stopped and human chorionic gonadotropin (hCG) will not be given (see section 2, under "Ovarian hyperstimulation syndrome"). In this case, your doctor will prescribe you a lower dose of follitropin alfa in the following treatment cycle.

Do not exceed the recommended dose.

How to use Pergoveris pre-filled pen
See the "Instructions for use" booklet enclosed to the package.

If you accidentally took a higher dosage
The effects of an overdose of Pergoveris are unknown, nevertheless, ovarian hyperstimulation syndrome (OHSS) may occur. However, this will only occur if human

chorionic gonadotropin (hCG) is administered (see section 2, under “Ovarian hyperstimulation syndrome”).

If you took an overdose, or if a child has accidentally swallowed some medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine
Do not take a double dose to compensate for a forgotten dose. Contact your doctor.

Adhere to the treatment regimen recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take the medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Pergoveris may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Most serious side effects
Contact the doctor immediately if you notice any of the side effects detailed below. The doctor might ask you to stop using Pergoveris.

<u>Allergic reactions</u>
Allergic reactions such as rash, skin redness, hives, swelling of the face with breathing difficulties, which sometimes can be serious. This side effect is very rare.

<u>Ovarian Hyperstimulation Syndrome (OHSS)</u>
- Lower abdominal pain together with nausea or vomiting, may be the symptoms of OHSS. This may indicate an over-reaction of the ovaries to the treatment and development of sacs of fluid or cysts (see section 2, under “Ovarian hyperstimulation syndrome”). This side effect is common. If this effect occurs, the doctor will need to examine you as soon as possible.
- OHSS may become severe when there is significant enlargement of the ovaries, decreased urine production, weight gain, breathing difficulties and/or possible fluid accumulation in the stomach or chest. This side effect is uncommon (may affect up to 1 in 100 patients).
- Complications of OHSS, e.g., twisting of ovaries or development of blood clots are rare (may affect up to 1 in 1,000 patients).
- Serious blood clotting complications (thromboembolic events), usually with severe OHSS, are very rare. This complication could cause chest pain, breathlessness, stroke or heart attack. In rare cases, this can also happen independently of OHSS (see section 2, under “Blood clotting problems [thromboembolic events: thromboembolism]“).

Additional side effects

<u>Very common</u> (may affect more than 1 in 10 patients):
- sacs of fluid within the ovaries (ovarian cysts)
- headache

- local reactions at the injection site such as pain, itching, bruising, swelling or irritation

Common (may affect up to 1 in 10 patients):
- diarrhea
- chest pain
- nausea and vomiting
- abdominal or pelvic pain
- abdominal cramps or bloating

Very rare (may affect up to 1 in 10,000 patients):
- your asthma may worsen

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). Do not freeze. Protect from light.
- After first opening, the pre-filled pen can be stored outside of the refrigerator (at 25°C) for a period of up to 28 days.
- Do not use the preparation if you notice that the preparation has been damaged, if the solution is not clear or contains particles. Do not use the medicine remaining in the pre-filled pen after 28 days.
- After injecting, safely discard the used needle.
- Do not discard medicines into the sewage drainage system or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What the medicine contains
The active ingredients are follitropin alfa and lutropin alfa
- Each Pergoveris pen (300 IU + 150 IU)/0.48 mL contains 300 IU of follitropin alfa and 150 IU of lutropin alfa in 0.48 mL and can supply two doses of Pergoveris 150 IU/75 IU.
- Each Pergoveris pen (450 IU + 225 IU)/0.72 mL contains 450 IU of follitropin alfa and 225 IU of lutropin alfa in 0.72 mL and can supply three doses of Pergoveris 150 IU/75 IU.
- Each Pergoveris pen (900 IU + 450 IU)/1.44 mL contains 900 IU of follitropin alfa and 450 IU of lutropin alfa in 1.44 mL and can supply six doses of Pergoveris 150 IU/75 IU.

In addition to the active ingredients, the medicine also contains:
Sucrose, L-arginine monohydrochloride, poloxamer 188, L-Methionine, phenol, disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate, water for injection.

Tiny amounts of concentrated phosphoric acid and sodium hydroxide are added to maintain a normal acidity level (pH).

What the medicine looks like and the contents of the package -
Pergoveris is provided as a clear, colorless to light yellow solution for injection, in a multi-dose pre-filled pen:

- Pergoveris (300 IU + 150 IU)/0.48 mL comes in a package which includes one multi-dose pre-filled pen and 5 disposable injection needles.
- Pergoveris (450 IU + 225 IU)/0.72 mL comes in a package which includes one multi-dose pre-filled pen and 7 disposable injection needles.
- Pergoveris (900 IU + 450 IU)/1.44 mL comes in a package which includes one multi-dose pre-filled pen and 14 disposable injection needles.

License holder and address: Merck Serono Ltd., 18 Hakishon St., Yavne 81220

Manufacturer and address: Merck Europe B.V., Amsterdam, The Netherlands

This leaflet was revised in March 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 160 56 35355 00

Instructions for use

Pergoveris®
pre-filled pen

تعليمات الاستعمال

پرچوفریس®
قلم جاهز للحقن

הוראות שימוש

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

Follitropin alfa/Lutropin alfa

MERCK

Table of contents

Important information about the Pergoveris pre-filled pen

- Read the Instructions for use and the Patient leaflet before using Pergoveris.
- 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 Pergoveris pen is intended for subcutaneous injection only.
- Only use the Pergoveris pen if your healthcare provider has trained you on how to use it correctly.
- Your healthcare provider will tell you how many Pergoveris pens you need to complete your treatment.
- Inject the medicine at the same time each day.

- 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

*IU – International Units

Note:

- The maximal dose you can set for the Pergoveris **(300 IU + 150 IU)/0.48 mL** pen is 300 IU.
- The maximal dose you can set for the Pergoveris **(450 IU + 225 IU)/0.72 mL** pen and the Pergoveris **(900 IU + 450 IU)/1.44 mL** pen is 450 IU.
- The dose setting knob can be turned in increments of 12.5 IU until the intended dose is reached.

Refer to the Patient leaflet for more information on the recommended dose regimen and always follow the dosage recommended by your doctor.

- 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.

Figure 1

Figure 2

Figure 3

Do not reuse needles.

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

Do not use the Pergoveris pen if it has been dropped, cracked or damaged, as this may cause injury.

How to use your Pergoveris 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.

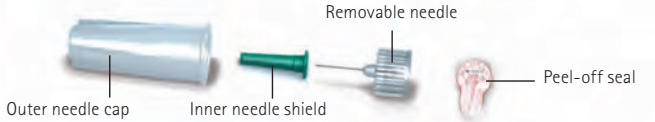
Using the treatment diary to record your daily injections allows you to verify every day that you received your full prescribed dose.

An example of a treatment diary using a **(450 IU + 225 IU)/0.72 mL pen**:

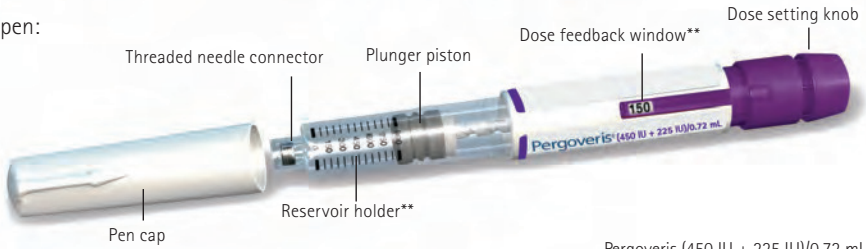
1 Treatment day number	2 Date	3 Time of injection	4 Pen volume (IU) (300 IU + 150 IU)/0.48 mL (450 IU + 225 IU)/0.72 mL (900 IU + 450 IU)/1.44 mL	5 Prescribed dose	6 Dose feedback window	7	8
					Amount set to inject	0	Amount to be set for a second injection
#1	10/06	19:00	450 IU + 225 IU	150 IU/75 IU	150	☑ if "0", injection complete	☐ if not "0", inject this amount ..... using a new pen
#2	11/06	19:00	450 IU + 225 IU	150 IU/75 IU	150	☑ if "0", injection complete	☐ if not "0", inject this amount ..... using a new pen
#3	12/06	19:00	450 IU + 225 IU	225 IU/ 112.5 IU	225	☐ if "0", injection complete	☑ if not "0", inject this amount 75 using a new pen
#3	12/06	19:00	450 IU + 225 IU	N/A	75	☑ if "0", injection complete	☐ if not "0", inject this amount ..... using a new pen

Get familiar with the Pergoveris pre-filled pen

The needle*:



The pen:



Pergoveris (450 IU + 225 IU)/0.72 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.

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

1.6. Check the name on the pen: "Pergoveris pre-filled pen".

1.7. Check the expiration date on the pen label (Figure 6).
Do not use the Pergoveris pen if the expiration date has passed or if "Pergoveris pre-filled pen" is not written on it.

Figure 4

Figure 5

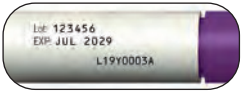


Figure 6

English

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

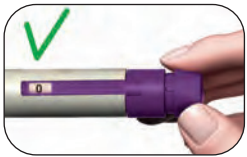


Figure 8

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.

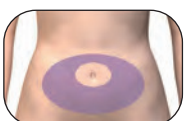


Figure 9

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.

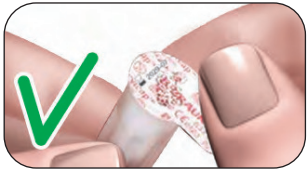


Figure 10

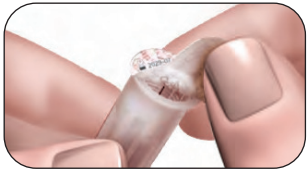


Figure 11

3.6. Screw the outer needle cap onto the threaded tip of the Pergoveris 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 Pergoveris 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

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**.

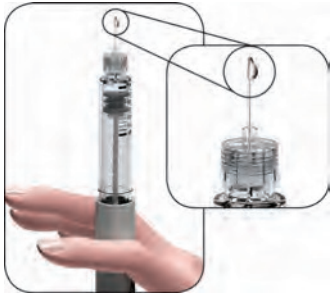


Figure 17

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:

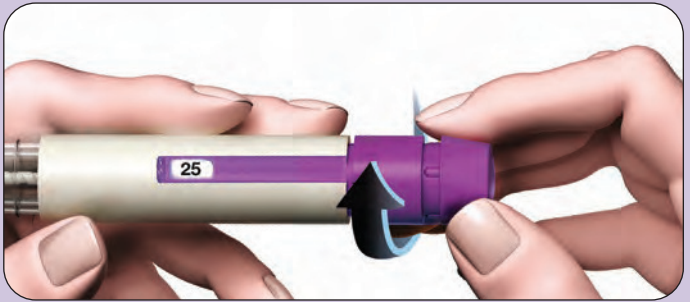


Figure 18

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

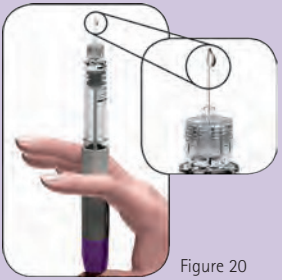


Figure 20

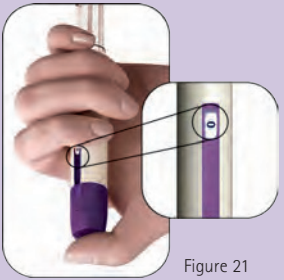


Figure 21

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

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.

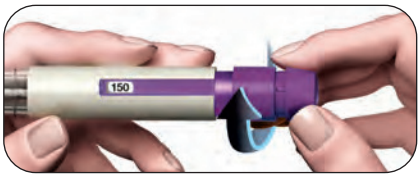


Figure 22

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

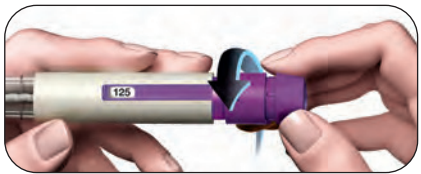


Figure 23

- 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 ❺ 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

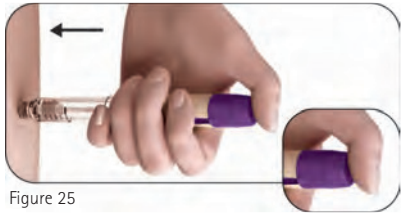


Figure 25

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".
- 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 26

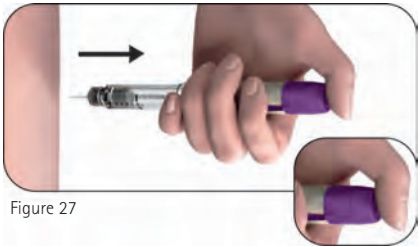


Figure 27

Step ⑥ Remove the needle after each injection

6.1. Place the outer needle cap on a flat surface.

6.2. Hold the Pergoveris pen firmly with one hand and slip the needle into the outer needle cap (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).

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.

Figure 28

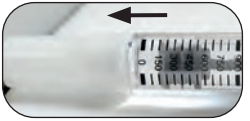


Figure 29

Do not reuse or share any used needle.

Figure 30

Figure 31

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).

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

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 ⑧ Store the Pergoveris 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.

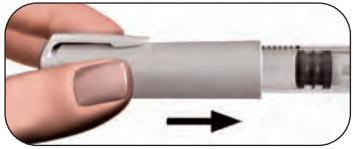


Figure 34

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

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

Contact your healthcare provider if you have questions.

Pergoveris pre-filled pen treatment diary

1 Treatment day number	2 Date	3 Time of injection	4 Pen volume (IU) (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 Amount set to inject	7 Dose feedback window 	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.

Pergoveris®
pre-filled pen

پرچوفریس®
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
محلول للحقن ضمن قلم جاهز للحقن