Package leaflet: Information for the user

Pergoveris (900 IU + 450 IU)/1.44 mL solution for injection in pre-filled pen
follitropin alfa/lutropin alfa

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pergoveris is and what it is used for

What Pergoveris is
Pergoveris contains two different active substances called “follitropin alfa” and “lutropin alfa”. Both belong to the family of hormones called “gonadotropins”, which are involved in reproduction and fertility.

What Pergoveris is used for
This medicine is used to stimulate the development of follicles (each containing an egg) in your ovaries. This is to help you get pregnant. It is for use in adult women (18 years old or above) who have low levels (severe deficiency) of “follicle stimulating hormone” (FSH) and “luteinising hormone” (LH). These women are usually infertile.

How Pergoveris works
The active substances in Pergoveris are copies of the natural hormones FSH and LH. In your body:
- FSH stimulates the production of eggs
- LH stimulates the release of the eggs.

By replacing the missing hormones, Pergoveris allows women with low levels of FSH and LH to develop a follicle. This will then release an egg, after an injection of the hormone “human chorionic gonadotropin (hCG)”. This helps the women to become pregnant.

2. What you need to know before you use Pergoveris

You and your partner's fertility should be evaluated before the treatment is started by a doctor experienced in treating fertility problems.

Do not use Pergoveris
- if you are allergic to follicle stimulating hormone (FSH), luteinising hormone (LH) or any of the other ingredients of this medicine (listed in section 6)
- if you have a brain tumour (in your hypothalamus or pituitary gland)
- if you have large ovaries or sacs of fluid within your ovaries (ovarian cysts) of unknown origin

- if you have unexplained vaginal bleeding
- if you have cancer in your ovaries, womb or breasts
- if you have a condition that would make a normal pregnancy impossible, such as an early menopause, malformed sex organs or benign tumours of the womb.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before using this medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Pergoveris.

Porphyria
Talk to your doctor before you start your treatment.If you or any member of your family have porphyria (an inability to breakdown porphyrins that may be passed on from parents to children).

Tell your doctor straight away if:
- your skin becomes fragile and easily blistered, especially skin that has been frequently exposed to sunlight
- you have stomach, arm or leg pain.

In case of above events your doctor may recommend that you stop treatment.

Ovarian hyperstimulation syndrome (OHSS)
This medicine stimulates your ovaries. This increases your risk of developing ovarian hyperstimulation syndrome (OHSS). This is when your follicles develop too much and become large cysts. If you get lower abdominal pain, gain any weight rapidly, feel sick or are vomiting or if you have difficulty in breathing, talk to your doctor straight away. They might ask you to stop using this medicine (see in section 4. under “Most serious side effects”).

In case you are not ovulating and if the recommended dose and schedule of administration are adhered to, the occurrence of severe OHSS is less likely. Pergoveris treatment seldom causes severe OHSS. This becomes more likely if the medicine that is used for final follicular maturation (containing human chorionic gonadotropin, hCG) is administered (see in section 3. under “How much to use” for details). If you are developing OHSS your doctor may not give you any hCG in this treatment cycle and you may be told not to have sex or that you should use a barrier contraceptive method for at least four days.

Your doctor will ensure, careful monitoring of the ovarian response, based on ultrasound and blood tests (oestradiol measurements) before and during the course of treatment.

Multiple pregnancy
When using Pergoveris, you have a higher risk of being pregnant with more than one child at the same time (“multiple pregnancy”, mostly twins), than if you conceived naturally. 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 at the right times.

To minimise the risk of multiple pregnancy, ultrasound scans as well as blood tests are recommended.

Miscarriage
When undergoing stimulation of your ovaries to produce eggs, you are more likely to have a miscarriage than the average woman.

Ectopic pregnancy
Women who have ever had blocked or damaged fallopian tubes (tubal disease) are at risk of pregnancy where the embryo is implanted outside the womb (ectopic pregnancy). This is whether the pregnancy is obtained by spontaneous conception or with fertility treatments.

Blood clotting problems (thromboembolic events)
Talk to your doctor before using Pergoveris 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 existing clots might become worse with Pergoveris treatment.

Tumours of sex organs
There have been reports of tumours 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 type of reaction to a similar medicine, talk to your doctor before using Pergoveris.

Children and adolescents
Pergoveris is not for use in children and adolescents below 18 years old.

Other medicines and Pergoveris
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Do not use Pergoveris with other medicines in the same injection. You can use Pergoveris with a licensed follitropin alfa preparation as separate injections, if prescribed by your doctor.

Pregnancy and breast-feeding
Do not use Pergoveris if you are pregnant or breast-feeding.

Driving and using machines
It is not expected that this medicine will affect your ability to drive or use machines.

Pergoveris contains sodium
Pergoveris contains less than 1 mmol sodium (23 mg) per dose that is to say essentially "sodium-free".

3. How to use Pergoveris

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine
- Pergoveris is intended to be given by injection just under the skin (subcutaneously). To minimise skin irritation, select a different injection site each day.
- Your doctor or nurse will show you how to use the Pergoveris pre-filled pen to inject the medicine.
- If they are satisfied that you can administer Pergoveris safely, you can then prepare and inject the medicine yourself at home.
- If you administer Pergoveris to yourself, please carefully read and follow the "Instructions for Use".

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

When you get the desired response, you will be given a single injection of human chorionic gonadotropin (hCG) 24 to 48 hours after your last Pergoveris injection. The best time to have sex is on the day of the hCG injection and the day after. Alternatively, intrauterine insemination or another medically assisted reproduction procedure may be performed based on your doctor's judgment.

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

If you use more Pergoveris than you should
The effects of an overdose of Pergoveris are unknown, nevertheless one could expect OHSS to occur. However this will only occur if hCG is administered (see in section 2. under "Ovarian hyperstimulation syndrome (OHSS)").

If you forget to use Pergoveris
Do not use a double dose to make up for a forgotten dose. Please contact your doctor.

If you have any further question on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most serious side effects
Contact your doctor straight away if you notice any of the below listed side effects. The doctor might ask you to stop using Pergoveris.

Allergic reactions
Allergic reactions such as rash, red skin, hives, swelling of your face with difficulty breathing can sometimes be serious. This side effect is very rare.

Ovarian hyperstimulation syndrome (OHSS)
- Lower abdominal pain together with nausea or vomiting. These may be the symptoms of ovarian hyperstimulation syndrome (OHSS). Your ovaries may have over-reacted to the treatment and formed large sacs of fluid or cysts (see in section 2. under "Ovarian hyperstimulation syndrome (OHSS)"). This side effect is common. If this happens, your doctor will need to examine you as soon as possible.
- The OHSS may become severe with clearly enlarged ovaries, decreased urine production, weight gain, difficulty in breathing and/or possible fluid accumulation in your stomach or chest. This side effect is uncommon (may affect up to 1 in 100 people).
- Complications of OHSS such as twisting of ovaries or blood clotting occur rarely (may affect up to 1 in 1 000 people).
- Serious blood clotting problems (thromboembolic events) usually with severe OHSS are found very rarely. This could cause chest pain, breathlessness, stroke or heart attack. In rare cases this can also happen independently of OHSS (see in section 2. under "Blood clotting problems (thromboembolic events)").

Other side effects

Very common (may affect more than 1 in 10 people):
- 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 people):
- diarrhoea
- breast pain
- feeling sick or vomiting
- abdominal or pelvic pain
- abdominal cramp or bloating.

Very rare (may affect up to 1 in 10 000 people):
- Your asthma may get worse.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pergoveris

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C). Do not freeze.
Store in the original package in order to protect from light.

Once opened, the pre-filled pen may be stored for a maximum of 28 days outside of the refrigerator (at 25°C). Do not use any medicine left in your pre-filled pen after 28 days.

Do not use Pergoveris if you notice any visible signs of deterioration, if the liquid contains particles or is not clear.

After the injection, dispose of the used needle safely.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pergoveris contains
The active substances are follitropin alfa and lutropin alfa.
- Each pre-filled pen of Pergoveris (900 IU + 450 IU)/1.44 mL contains 900 IU (International Units) of follitropin alfa and 450 IU of lutropin alfa in 1.44 mL and can deliver six doses of Pergoveris 150 IU/75 IU.

The other ingredients are
- Sucrose, arginine monohydrochloride, poloxamer 188, methionine, phenol, disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate and water for injections. Tiny amounts of concentrated phosphoric acid and sodium hydroxide are added to keep acidity levels (pH levels) normal.

What Pergoveris looks like and contents of the pack
Pergoveris is presented as a clear, colourless to slightly yellow solution for injection in a mulitidose pre-filled pen:

- Pergoveris (900 IU + 450 IU)/1.44 mL is supplied in packs of 1 multidose pre-filled pen and 14 disposable injection needles.

Marketing Authorisation Holder
Merck Serono Ltd, 5 New Square, Bedfont Lakes Business Park, Feltham, Middlesex, TW14 8HA, UK

Manufacturer
Merck Serono S.p.A, Via delle Magnolie 15 (Zona industriale), I-70026 Modugno (Bari), Italy

This leaflet was last revised in December 2021.

Instructions for Use

Pergoveris
(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
Follitropin alfa/Lutropin alfa

Table of Contents

Important information about the Pergoveris pre-filled pen

- Read the Instructions for Use and the Package Leaflet before using your Pergoveris 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 Pergoveris pre-filled pen is for subcutaneous injection only.
- Only use the Pergoveris pre-filled pen if your healthcare provider trains you on how to use it correctly.
- Your healthcare provider will tell you how many Pergoveris pre-filled pens you need to complete your treatment.
- Give yourself the injection 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.

Note:

- The maximum dose you can dial is 300 IU for the (300 IU + 150 IU)/0.48 mL presentation.
- The maximum dose you can dial is 450 IU for both the (450 IU + 225 IU)/0.72 mL and the (900 IU + 450 IU)/1.44 mL presentations.
- The dose setting knob turns in increments of 12.5 IU to reach your intended dose.

Refer to the Package leaflet for more information on the recommended dose regimen and always follow the dose recommended by your healthcare provider.

- 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).

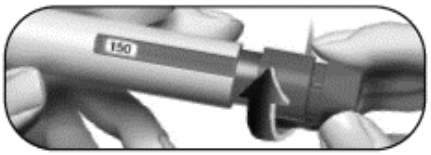


Fig. 1

b. Verify a complete injection (Figure 2).

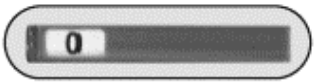


Fig. 2

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

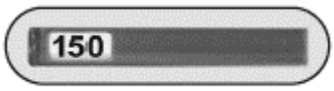


Fig. 3

- 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 Pergoveris pre-filled pen if it has been dropped, or the pen is cracked or damaged as this can cause injury.

How to use your Pergoveris 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.

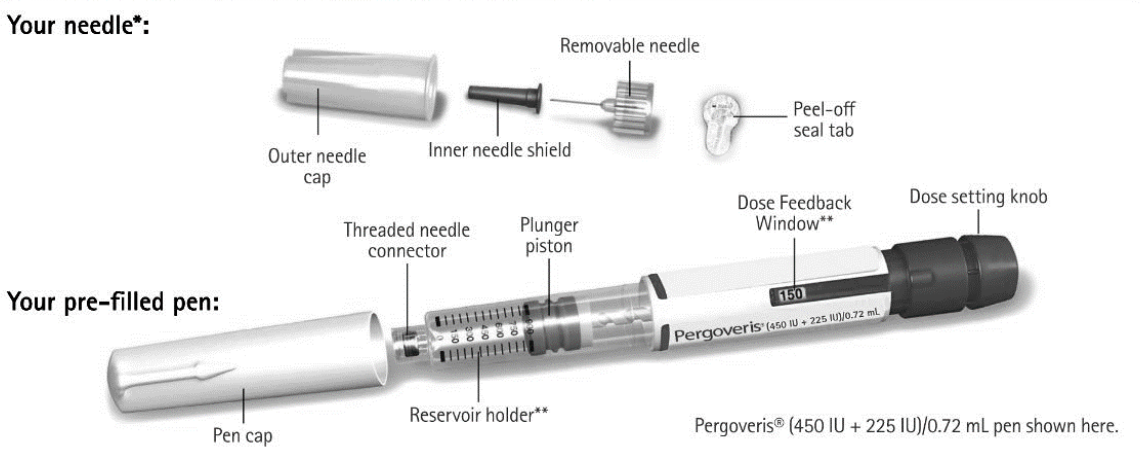
- Record the treatment day number (column 1), date (column 2), time of your injection (column 3), and volume of your pen (column 4).
- Record your prescribed dose (column 5).
- Check you dial the right dose before injecting (column 6).
- After injection, read the number shown in the **Dose Feedback Window**.
- 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 youself 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 in the next row (column 6).

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 using a (450 IU + 225 IU)/0.72 mL pen:

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 Dose Feedback Window	7	8
					Amount Set to Inject	Amount to Be Set for a Second Injection 0	
#1	*10/06*	19:00	*450 IU + 225 IU*	*150 IU/ 75IU*	*150*	☑ if "0", injection complete	☐ if not "0", need second injection Inject this amount .....using new pen
#2	*11/06*	19:00	*450 IU + 225 IU*	*150 IU/ 75IU*	*150*	☑ if "0", injection complete	☐ if not "0", need second injection Inject this amount .....using new pen
#3	*12/06*	19:00	*450 IU + 225 IU*	*225IU/ 112.5IU*	*225*	☐ if "0", injection complete	☑ if not "0", need second injection Inject this amount .*75*..using new pen
#3	*12/06*	19:00	*450 IU + 225 IU*	*N/A*	*75*	☑ if "0", injection complete	☐ if not """, need second injection Inject this amount .....using new pen

Get familiar with your Pergoveris pre-filled pen



Pergoveris® (450 IU + 225 IU)/0.72 mL pen shown here.

* For illustration 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.

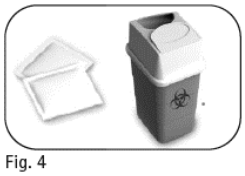


Fig. 4

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).


Fig. 5

1.5 Use your hand to remove the Pergoveris 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 Pergoveris.

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

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

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).

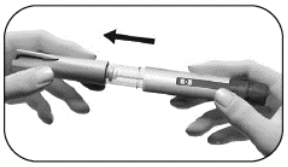


Fig. 7

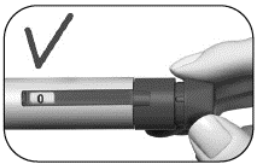


Fig. 8

Choose your injection site:

2.4 Your healthcare provider should show you the injection sites to use around your stomach area (Figure 9). To 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.

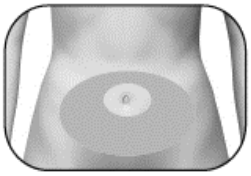


Fig. 9

Step 3 Attach your needle

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

Re-using needles can cause infections

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).

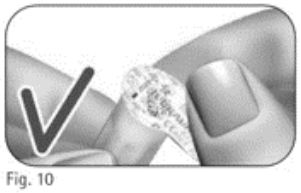


Fig. 10

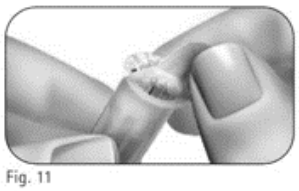


Fig. 11

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.

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

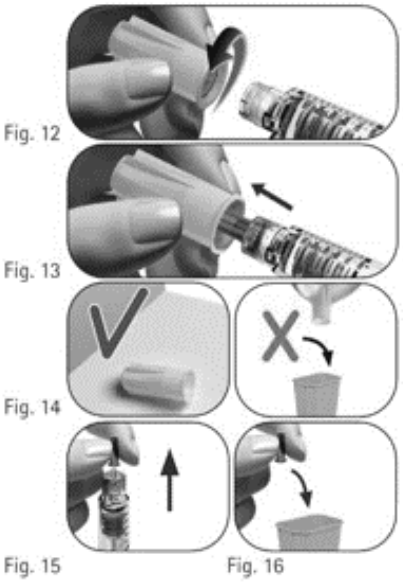
3.8 Put it aside for later use (Figure 14).

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 Pergoveris 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.

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, 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	It is NOT required to check for a droplet of liquid. Proceed directly to **Step 4 Dial your dose.**

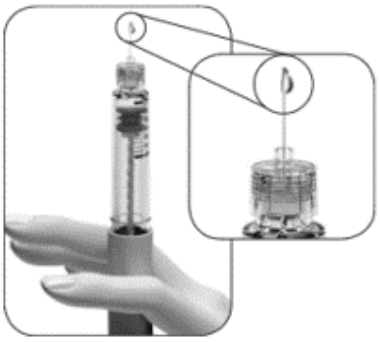


Fig. 17

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

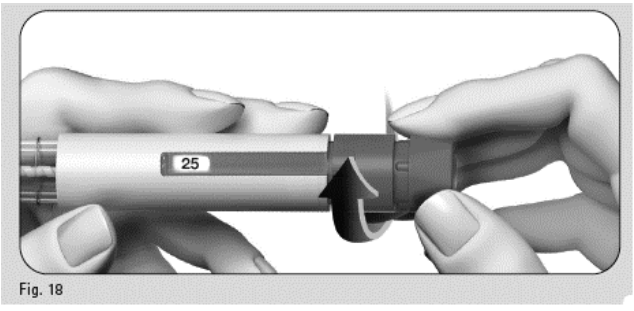


Fig. 18

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".

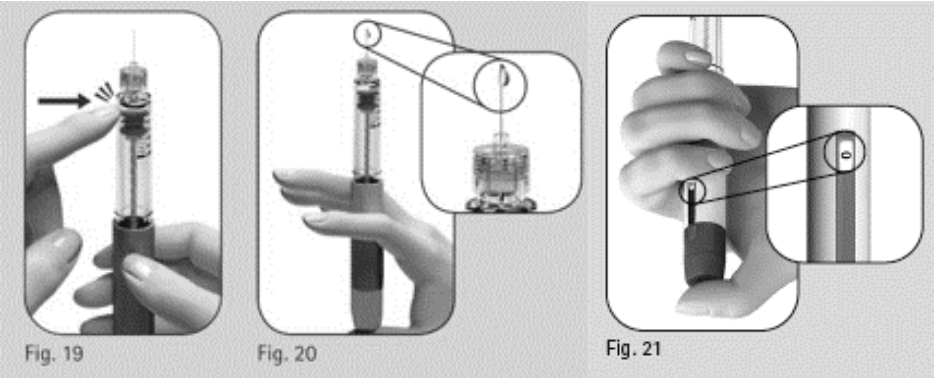


Fig. 19 Fig. 20 Fig. 21

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** 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

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.

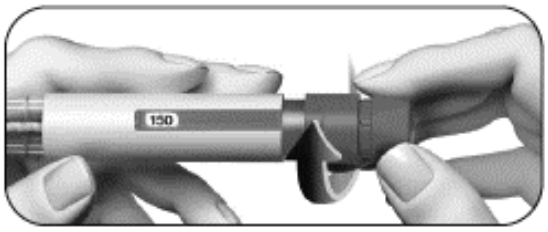


Fig. 22

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

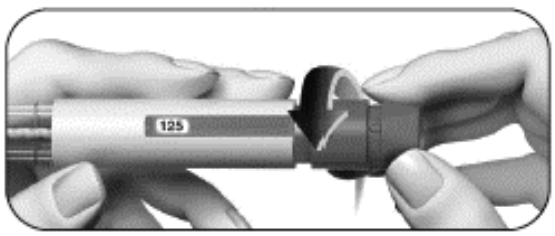


Fig. 23

- 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).

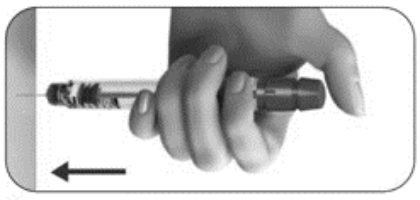


Fig. 24

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).

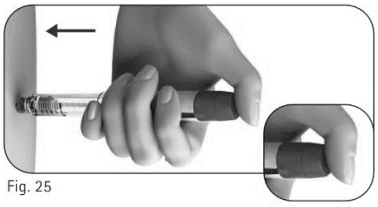


Fig. 25

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).

- 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.

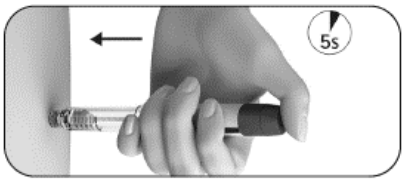


Fig. 26

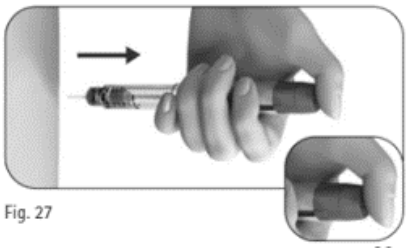


Fig. 27

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

Step 6 Remove the needle after each injection

6.1 Place the outer needle cap on a flat surface.

6.2 Hold the Pergoveris pre-filled 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).

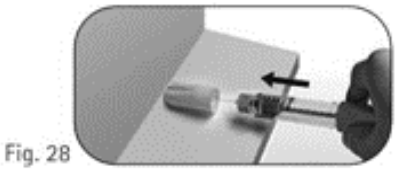


Fig. 28

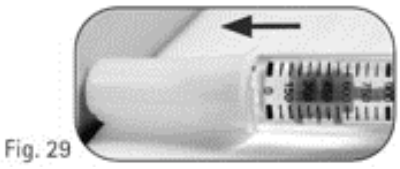


Fig. 29

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 (Figuer 31). Handle the needle with care to avoid getting injured by the needle.

Do not reuse or share any used needle.


Fig. 30 Fig. 31

Step 7 After the injection

7.1 Check you have given a complete injection
- Check that the Dose Feedback Window shows “0” (Figure 32).

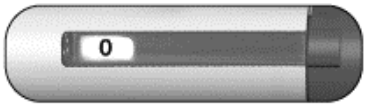


Fig. 32

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 pre-filled 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 through 8.

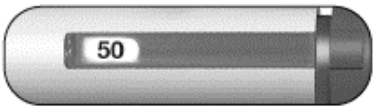


Fig. 33

Step 8 Storethe Pergoveris pre-filled pen

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

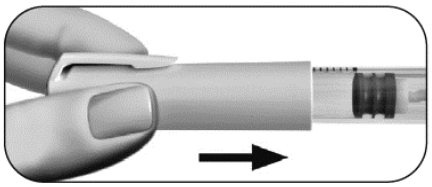


Fig. 34

8.2 Store the pen in its original packaging in a safe place and as indicated in the Package Leaflet.

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

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

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 Dose Feedback Window Amount Set to Inject	7 Amount to Be Set for a Second Injection 0	8
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen
	/	:				☐if "0", injection complete	☐if not "0", need second injection Inject this amount ....using new pen

This Instructions for Use has been last revised in: 01/2023