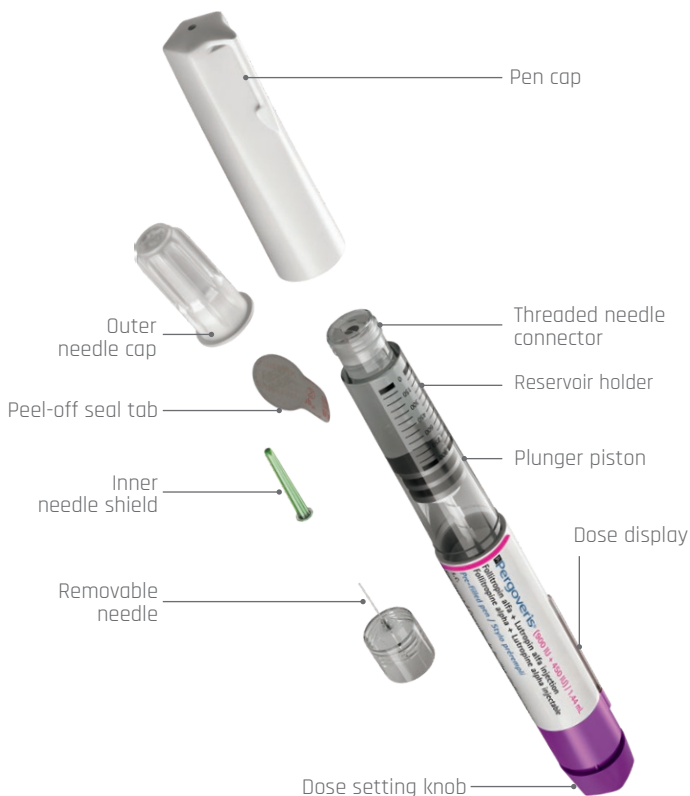


Pergoveris®

(follitropin alfa and lutropin alfa for injection)

A step-by-step guide to your

PERGOVERIS® Pen



PERGOVERIS® PEN AVAILABLE IN:

300 IU r-hFSH/150 IU r-hLH in 0.48 mL

450 IU r-hFSH/225 IU r-hLH in 0.72 mL

900 IU r-hFSH/450 IU r-hLH in 1.44 mL

r-hFSH = recombinant human follicle-stimulating hormone;
r-hLH = recombinant human luteinizing hormone



**EMD
SERONO**

About

PERGOVERIS[®]

What is PERGOVERIS[®]?

PERGOVERIS[®] is a combination of GONAL-*f*[®] (follicle-stimulating hormone or FSH) and LUVERIS[®] (luteinizing hormone or LH). It comes as a liquid formulation, in a pre-filled pen device, to be administered “*subcutaneously*” or “*under the skin*”.

What is PERGOVERIS[®] used for?

PERGOVERIS[®] is used to stimulate follicle growth for ovulation in women who do not release enough FSH and LH naturally, and do not ovulate.

Before PERGOVERIS[®] treatment, be sure to ask your doctor...

- How long will my treatment last?
- How are you monitoring my response?

When should PERGOVERIS[®] not be used?

Do not use PERGOVERIS[®] if you have:

- Hypersensitivity to GONAL-*f*[®], LUVERIS[®], or any ingredient in PERGOVERIS[®]
- Primary ovarian failure or anovulation with normal levels of FSH and LH
- Uncontrolled thyroid or adrenal gland problems
- Tumours of the hypothalamus or pituitary gland
- Ovarian enlargement or cyst of unknown cause
- Gynecological bleeding of unknown cause
- Sex hormone dependent tumours of the reproductive tract (and related organs)
- Current pregnancy or lactation
- A condition which would make a normal pregnancy impossible, such as:
 - Premature menopause
 - Malformation of reproductive organs
 - Specific tumours of the uterus, including severe uterine fibroids

What are some side effects I could see with PERGOVERIS[®]?

- Like all medicines, PERGOVERIS[®] may cause side effects; some people commonly experience abdominal pain, pelvic pain, breast pain, constipation, painful menstruation, stomach or intestinal gas, headache, nausea and reactions at the injection site (pain, redness, itching, bruising, swelling and/or irritation)

- There is a risk of developing **ovarian hyperstimulation syndrome (OHSS)** – the early warning signs are severe abdominal pain, nausea, vomiting and weight gain; OHSS can develop quickly, so if you experience any of these symptoms, contact your doctor immediately
- In serious, but rare cases, OHSS with clearly enlarged ovaries can include buildup of fluid in the abdomen or chest, as well as more serious complications (i.e., abnormal blood clotting); in rare cases, abnormal blood clotting can occur, independent of OHSS
- Ectopic pregnancy (i.e., embryo implanted outside the uterus) may occur, especially in women with history of prior disease/scarring of the Fallopian tubes

This is not a complete list of side effects. If you experience any of the conditions listed above or any unexpected side effect, please contact your doctor or pharmacist.

What interactions should I be aware of with PERGOVERIS®?

- Please tell your doctor or pharmacist if you are taking (or have recently taken) any other medicines, including over-the-counter products
- PERGOVERIS® should not be administered with other medications in the same injection; it may be given at the same time as GONAL-f® in a separate injection, if prescribed by your doctor

How do I use PERGOVERIS® properly?

- Always take PERGOVERIS® exactly as your doctor or Healthcare Professional (HCP) has instructed; with professional guidance, you can learn to inject yourself, in the comfort and privacy of your home

Try to inject PERGOVERIS® at around the same time each day.

Usual starting dose:

150 IU FSH and 75 IU LH

BUT you may be instructed to start on a different dose. ALWAYS take the dose you have been prescribed.

If you missed a dose of PERGOVERIS®, do not take a double dose, please contact your doctor.

- Based on your response, your doctor may increase your dose of GONAL-*f*®
- Once you reach the desired response, a single injection of another hormone – human chorionic gonadotropin (hCG) – is given, 24 to 48 hours after the last injection of PERGOVERIS®
- After your hCG injection...
 - **Timed intercourse:** it is recommended that you have sexual intercourse on the day of, and the day following administration of the hCG
 - **Intrauterine insemination (IUI):** follow the instructions provided by your HCP
 - **In vitro fertilization (IVF):** follow the instructions provided by your HCP
- If you have an excessive response, PERGOVERIS® should be stopped and hCG withheld; your doctor may prescribe a lower dose of PERGOVERIS® for the next cycle

Every treatment is individualized, according to your own specific needs – it is very important that you keep your appointments and follow your doctor's instructions.

What should I do when I cannot push the injection button to deliver the dose?

When you cannot push the injection button down, it means your pen is empty and it is unable to provide you with your desired dose; you may still see a small amount of medication remaining in the pen – this is normal

Storing your PERGOVERIS® pen

- Before first use, store at 2–8°C (refrigerator)
- Do not freeze
- Protect from light
- After first use, store at or below 25°C (room temperature), for a maximum of 28 days
- Do not use after expiry date
- Do not use if liquid contains particles or is not clear
- Never store pen with needle still attached
- Dispose of used needles safely
- Keep in safe place, away from children

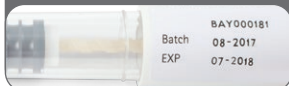
Step 1: Before you start using PERGOVERIS® pre-filled pen



- Wash your hands with soap and water. It is important that your hands and all materials are as clean as possible
- On a clean surface, (e.g., clean table or kitchen surface) lay out everything you will need:

- 1 PERGOVERIS® pre-filled pen
- 2 One removable injection needle; 1/2 inch 29 gauge (use the single-use disposable needles provided with the PERGOVERIS® pen)
- 3 Alcohol swabs
- 4 Sharps disposal container (not shown)

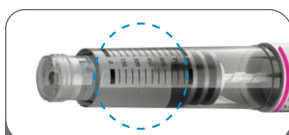
IMPORTANT! Verify the expiration date on the label - do not use expired medication.



Step 2: Getting your PERGOVERIS® pen ready for injection



- Take off the pen cap



IMPORTANT! If the solution is NOT clear, or if it contains particles, do not use the pen. Contact your clinic or pharmacist for further instruction.

- Take a close look at the solution in the reservoir holder to make sure the solution is clear and free of particles
- If your solution is clear and free of particles, wipe the end of the threaded tip (containing the rubber centre) using an alcohol swab



- Verify that the dose display is set to "0"



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

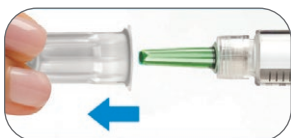
- Prepare your needle for injection
 - Get a new needle – only use the "single-use" needles supplied
 - Hold the outer needle cap firmly
 - Check that the peel-off seal on the outer needle cap is not damaged or loose
- Remove the peel-off seal

STEP 3: Attach the needle



- Screw the threaded tip of the PERGOVERIS® pen into the outer needle cap, and twist clockwise until you feel a light resistance

IMPORTANT! Do not attach the needle too tightly, as it may be difficult to remove the needle after the injection.



- Remove the outer needle cap by pulling it straight off – put it aside for later use
- Do not throw away the outer needle cap; you will need it for removing the needle from the pen



- Hold the PERGOVERIS® pen with the needle pointing upwards
- Carefully remove the green inner shield by pulling it straight off and discard it

IMPORTANT! Do not recap the needle with the green inner shield, as this can cause you to prick yourself.

If this is NOT a brand new PERGOVERIS® pen
(you have done previous injections with this pen),
then proceed to Step 4 - Setting your dose.



If this is a brand new pen that you are using for the first time, look closely at the tip of the needle for a tiny drop of fluid. If you see a tiny drop of fluid, move on to Step 4 - Setting your dose. If you do not see a tiny drop of fluid, please refer to the section - *Preparing your new PERGOVERIS® pre-filled pen for first-time use.*

IMPORTANT! Only check for drops with a brand new pen - this step is not required if you are doing additional injections using the same pen.

STEP 4: Setting your dose



- Turn the dose setting knob forward (or clockwise) until your prescribed dose shows in the dose display; do not push or pull the dose setting knob while you turn it

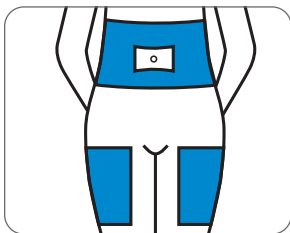
IMPORTANT! To avoid breaking the pen, be sure you only twist the end of the dose setting knob.



- If you have turned the dose setting knob past your prescribed dose, turn the knob backwards (or counter-clockwise) to correct the dose

IMPORTANT! Check that the dose display shows your prescribed dose before you move to the next step.

STEP 5: Injecting your dose



- Choose an injection site in the area your doctor or nurse has told you to give the injection, such as your upper thigh or abdomen

IMPORTANT! To minimize skin irritation, select a different injection site each day.



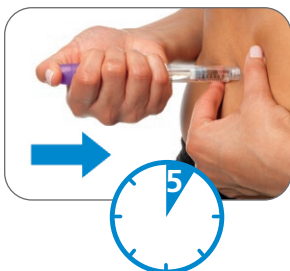
- Clean the skin by wiping the area (about the size of a teabag) with an alcohol swab; allow the site to dry and set the alcohol swab to the side



- Check again to make sure the dose display is showing the correct dose; if it is not, you can adjust by turning the dose setting knob either clockwise or counter-clockwise (see *Step 4 – Setting your dose*)



- Inject the dose as you were trained to do by your doctor or nurse:
 - Hold the pen in one hand, use your other hand to gently squeeze the skin together to make a raised area at the injection site
 - Insert the needle at a 90° angle into the skin
 - Press the dose knob down as far as it will go and hold it to complete the full injection; the larger the dose, the longer it will take to inject



- Hold the dose knob down for a minimum of 5 seconds to ensure you inject the full dose
- After at least 5 seconds, keeping the dose setting knob pressed down, remove the needle from your skin
- Then release the dose setting knob

IMPORTANT! Do not release the dose setting knob until you have removed the needle from your skin.

STEP 6: After the injection



- When the injection is finished, use the clean side of your alcohol swab to gently clean the injection site; if there is minor oozing, you may need to apply a small amount of pressure for a few seconds



- Check to make sure you have given the complete injection – the dose display should show “0”

IMPORTANT! If the dose display shows a number higher than “0”, the PERGOVERIS® pen is empty and you have not received your full prescribed dose.

IMPORTANT! Always make sure to use a new needle for each injection.

- The number shown in the dose display will indicate the missing amount (which you must inject using a new pen)
- If this happens, prepare a new pen like your doctor or nurse has shown you, and set the dose to the exact number displayed on the dose display of the empty pen; now you are ready to complete your daily dose
- Make sure you check for tiny drops of fluid if you are using a brand new PERGOVERIS® pen for the first time

Removing the needle after each injection:

- Place the outer needle cap on a flat surface
- Hold the PERGOVERIS® pen firmly with one hand, and slip the needle into the outer needle cap; be careful not to prick yourself with the needle
- 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 counter clockwise; dispose of the used needle safely
- Recap the pen and store as instructed



IMPORTANT! Never reuse any used needle. Never share needles. Never store the pen with the used needle still attached.

Preparing your new PERGOVERIS® pre-filled pen for first time use



**If you do not see
a tiny drop(s),
do the following:**



- Gently turn the dose setting knob clockwise until it reads "25" in the Dose Display; you can turn the dose knob backwards if you turn it past "25"
- Hold the pen with the needle pointing upward
- Tap the reservoir holder gently
- Press the dose setting knob as far as it will go. A tiny drop of fluid will appear at the tip of the needle (this fluid is part of the overfill from the pre-filled pen)
- Verify that the Dose Display reads "0"
- You may need to repeat this step if you do not see a tiny drop of liquid appearing at the tip of the needle
- Once you see a drop of liquid at the tip of the needle, move on to *Step 4 – Setting your dose*

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You are not alone.

Where can you get help and find more information?

momentum

The *MOMENTUM* patient services program is a free and confidential service that offers customized patient support, including injection assistance, to individuals using EMD Serono fertility products.

 **fertility.mymomentum.ca**

Our comprehensive patient website is designed to provide:

- Technical support including downloadable injection guides and videos
- Frequently asked questions on EMD Serono products

 **1-800-387-8479**

- Our *MOMENTUM* toll-free helpline is available 24 hours a day, 7 days a week
- Regular hours are 8:00 a.m. to 8:00 p.m. (Eastern Time), Monday to Friday
- An after-hour pager service is available for urgent inquiries that cannot wait until the following business day. Simply leave your name, reason for calling, and your phone number, and a registered nurse will return your call in a timely manner

***MOMENTUM* is available in over 250 languages
through the assistance of certified translators.**

MOMENTUM will not comment on individual diagnosis or treatment questions, laboratory results or products not manufactured by EMD Serono. You should discuss those with your healthcare provider. *MOMENTUM* is a source of educational support sponsored by EMD Serono, Canada, and is not intended to replace discussions with your healthcare provider.


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