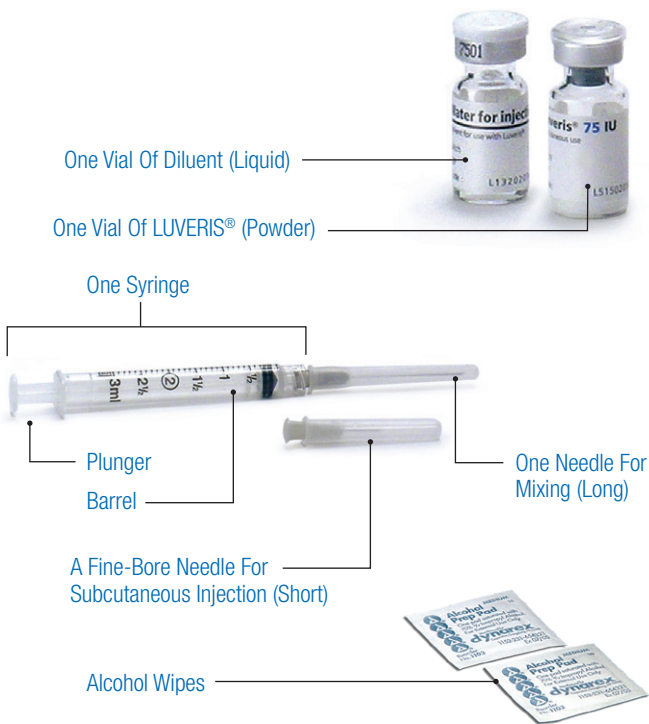




Luveris®

(LUTROPIN ALFA FOR INJECTION)

Administration and storage instructions



ADMINISTRATION

REVIEW THESE STEPS BEFORE YOU ADMINISTER LUVERIS

Before you begin:

- Lay out the above materials on a clean surface.
- Wash hands well with soap and water.
- If you use your kitchen to prepare the injection, ensure that all medicines and needles are kept well away from food. As for the injection itself, it can be given in any room where you feel comfortable.



EMD
SERONO

Drawing up the diluent



Step 1

You should have one vial containing diluent (clear liquid) and one vial containing LUVERIS (white powder).

Remove the protective cap from the vial containing the diluent.

Use an alcohol wipe to cleanse the metal ring and rubber stopper.

Discard the alcohol wipe.



Step 2

Remove the syringe from its package and carefully uncover the needle.

Do not let the needle touch any surface.

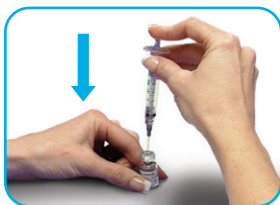
Pull the plunger back until it is at the line next to the number showing the amount of diluent that you need to draw up as advised by your healthcare provider (for example, 1 cc).



Step 3

Place the vial on a clean, flat surface.

Push the needle through the centre of the rubber stopper on the vial.



Step 4

Push the plunger all the way in.



Step 5

Keeping the needle in the vial, lift the vial and turn it upside down.

IMPORTANT: Be sure you completely cover the needle tip with liquid before pulling back on the plunger.

Slowly pull the plunger back until you see the required amount of diluent in the syringe.

Remove the syringe and carefully replace the cap on the needle. Discard the vial with any unused diluent in the disposal container.

Preparing and drawing up the medication



Step 6

Remove the protective cap from the LUVERIS powder vial. Use an alcohol wipe to cleanse the metal ring and rubber stopper.

Discard the alcohol wipe.

Pick up syringe containing the diluent and carefully remove the cap.



Step 7

Through the centre of the rubber stopper on the LUVERIS powder vial, slowly inject the required amount of diluent into the powder vial.



Step 8

Leaving the needle in the vial, gently rotate the vial between your fingers until all of the powder is dissolved. Check that the solution is clear and colourless.

Do not shake.

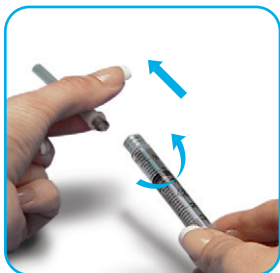
IMPORTANT: Do not use if the solution is cloudy, discoloured, or contains particles.



Step 9

After the powder has dissolved, turn the vial upside down, and gently draw up the entire contents of the vial into the syringe. Be careful not to pull the plunger out of the syringe. It may help to slowly tip the vial.

IMPORTANT: Be sure you completely cover the needle tip with liquid before pulling back on the plunger.



Step 10

Hold the syringe with the needle pointing upwards.

Create an airspace at the top of the barrel by gently pulling the plunger back.

Carefully recap the needle, then twist and remove it.

Getting ready for the injection



Step 11

Replace the long mixing needle with the fine-bore short needle for injection.

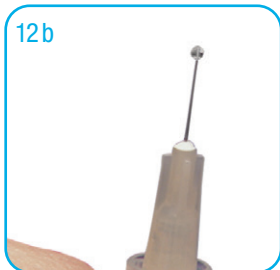
Twist to attach, and remove the cap.



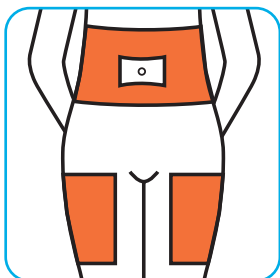
Step 12

a. Hold the syringe with the needle pointing upwards and gently flick the syringe if there are any visible air bubbles.

b. Gently push the plunger upwards until a small droplet of liquid appears at the tip of the needle, and replace the cap on the needle and place the syringe on a clean surface.



IMPORTANT: Do not worry if you are unable to remove very tiny bubbles; they will do you no harm.



Step 13

Select the site of injection (e.g. top of thigh, tummy) using the injection site diagram provided by your healthcare provider.

Choose a different site each day.



Step 14

Wipe the chosen area with an alcohol swab, cleansing an area of approximately 5 cm x 5 cm (about the size of a square tea bag).

Lay the used side of the swab on the clean working surface or the wrapper.

Step 15

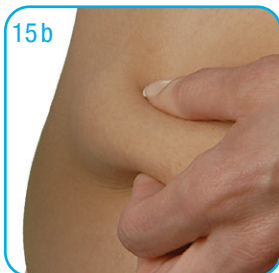
a. Pick up the syringe and remove the cap from the needle.

Invert the needle and, using the hand with which you write, hold the syringe like a pencil or as if “throwing a dart”.

b. With your other hand, gently squeeze the skin together to make a little elevation at the injection site.



15a



15b

Step 16

Using a “dart-like motion”, insert the needle at a 90° angle. You need very little force but quick action.

Inject the solution by gently pushing on the plunger with your index finger.



Step 17

Take as much time as you need to inject all the solution.

As you release the skin from your grip, withdraw the needle by pulling it straight out.



Step 18

Clean skin with the clean side of the alcohol wipe using a circular motion.

If there is minor oozing at the injection site you may need to apply a small amount of pressure.

Once you have finished your injection, immediately discard all the needles and syringe (without recapping the needle) into the disposal container.



Frequently Asked Questions

What is LUVERIS?

LUVERIS (lutropin alfa for injection) is a recombinant human luteinizing hormone (r-hLH). Lutropin alfa is produced by recombinant DNA technology in a Chinese Hamster Ovary (CHO) mammalian cell expression system.

LUVERIS is usually prescribed in conjunction with GONAL-*f*[®] (follitropin alfa for injection). GONAL-*f* is also a gonadotropin hormone produced by recombinant DNA technology. It consists of highly purified FSH (follicle stimulating hormone), and contains no LH (luteinizing hormone).

Why have I been prescribed LUVERIS and GONAL-*f*?

Your doctor has probably prescribed LUVERIS to be given with GONAL-*f* because your pituitary gland does not release FSH or LH. This means that the follicles are unable to develop and mature, so ovulation cannot take place. LUVERIS provides you with LH that may be necessary to be given along with GONAL-*f*, which provides you with FSH. FSH is necessary for the recruitment, growth, and maturation of the ovarian follicles which contain eggs known as ova or oocytes. The addition of LUVERIS to GONAL-*f* may enhance this process. This occurs during the first half of the female reproductive cycle. After LUVERIS and GONAL-*f* are given to help develop ovarian follicles, another hormone, hCG (human chorionic gonadotropin), may be given mid-cycle to mature the eggs and cause ovulation.

Who should not take LUVERIS?

LUVERIS is contraindicated for safety reasons in the presence of:

- Hypersensitivity to LUVERIS or to any ingredient in the formulation or component of the container
- Uncontrolled thyroid or adrenal failure
- Active, untreated tumours of the hypothalamus and pituitary gland
- Pregnancy or lactation
- Ovarian, uterine, or mammary carcinoma
- Ovarian enlargement or ovarian cyst unrelated to polycystic ovarian disease and of unknown origin
- Abnormal uterine bleeding of unknown origin

LUVERIS must not be used when a condition exists which would make a normal pregnancy impossible, such as:

- Primary ovarian failure
- Malformations of sexual organs incompatible with pregnancy
- Fibroid tumours of the uterus incompatible with pregnancy

How is LUVERIS administered?

LUVERIS must be reconstituted with supplied Sterile Water for Injection using aseptic technique prior to subcutaneous administration.

Dissolve the contents of the vial of LUVERIS in 1 mL Sterile Water for Injection, USP. GONAL-*f* should be reconstituted and administered as directed in the prescriber labelling for this product. Administer entire contents of the vial SUBCUTANEOUSLY. For single use. Use immediately after reconstitution. Any unused reconstituted material should be discarded. Mix gently. Do not shake.

Are there any side effects with LUVERIS?

As with any drug, you may experience side effects when taking LUVERIS. In clinical trials, the most common side effects (experienced by more than 2% of patients) were headache, pelvic and abdominal pain, nausea, OHSS, breast pain, ovarian cysts, flatulence, injection site reactions, general pain, constipation, fatigue, painful menstruation, ovarian disorder, dysmenorrhea, diarrhea and upper respiratory tract infections. When taking LUVERIS, there is a risk of developing ovarian hyper-stimulation syndrome (OHSS). The early warning signs of development of OHSS are severe abdominal pain, nausea, vomiting and weight gain. Since OHSS develops rapidly, if you experience any of these symptoms, contact your doctor immediately.

Should I be concerned about interactions with other medications?

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Studies have shown that co-administration of LUVERIS and GONAL-*f* does not significantly alter the activity, stability, pharmacokinetic or pharmacodynamic properties of either active substance. No other clinically significant drug interaction has been reported during LUVERIS therapy.

What do I do if I missed a dose or overdose?

Missed dose: If you forget to take LUVERIS, do not take a double dose. In the case of a forgotten dose, please contact your doctor.

Overdose: The effects of an overdose of LUVERIS are unknown, nevertheless there is a possibility that ovarian hyperstimulation syndrome may occur. If you inject more medication at one time than you were prescribed, you should contact your doctor.

What are the other important points to remember?

- Store LUVERIS in the refrigerator or at stable room temperature (2-25°C).
- Avoid exposure to extreme heat or cold and store away from light.
- Always check the expiry date before use – never use expired LUVERIS.
- Do not use if solution contains particles or is not clear.
- Be sure to use the correct amount of diluent.
- Only make up the LUVERIS solution when you are ready to use it.
- Check site of previous injection, and choose a different site each day.
- Inject LUVERIS at around the same time each day.
- Discard any unused solution.
- Store the medicine out of the reach of children.
- For additional information, please refer to the package insert that came with your medication, or the latest approved product monograph.

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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References:

1. Luveris® Product Monograph. EMD Serono, June 10, 2019
2. Gonal-f® Product Monograph. EMD Serono, May 3, 2019.

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