

PERGOVERIS POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Follitropin alfa and Lutropin alfa (150IU, 75IU)

What is in this leaflet

1. What Pergoveris Powder and Solvent for Solution for Injection is used for
2. How Pergoveris Powder and Solvent for Solution for Injection works
3. Before you use Pergoveris Powder and Solvent for Solution for Injection
4. How to use Pergoveris Powder and Solvent for Solution for Injection
5. While you are using Pergoveris Powder and Solvent for Solution for Injection
6. Side effects
7. Storage and Disposal of Pergoveris
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Pergoveris is used for

This medicine is used to stimulate the development of follicles (each containing an egg) in your ovaries 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.

Before you use Pergoveris

- When you must not use it

- If you are allergic to follicle stimulating hormone (FSH), luteinising hormone (LH) or any of the other ingredients of this medicine
- 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
- If you or any member of your family have porphyria
- If you or any member had blood clots in the leg or in the lung, or a heart attack or stroke.

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

- Before you start to use it

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

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not use Pergoveris with other medicines in the same injection, except for follitropin alfa, if prescribed by your doctor.

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. It comes as a powder and liquid, which you need to mix together and then use immediately.

Your doctor or nurse will show you how to prepare and inject this medicine.

They will supervise your first injection.

If they are satisfied that you can administer Pergoveris safely, you can then prepare and inject the medicine yourself at home.

When you do this, please carefully read and follow the instructions hereafter called “How to prepare and use the Pergoveris powder and solvent” supplied in the pack with Pergoveris

Where to inject

Use a different injection site each time you inject to lessen the risk of skin irritation.

Suitable injection sites are:

- Stomach (except around navel and waistline)
- Thighs (front and sides except at groin and knee).

- How much to use

Your doctor will tell you how much Pergoveris to inject.

The usual starting dose is one vial of Pergoveris every day.

- According to your response, your doctor may decide to add every day a dose of follitropin alfa 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 (IUI) may be performed. If your body responds too strongly, your treatment will be stopped and you will not be given any hCG. In this case, your doctor will give you a lower follitropin alfa dose in the following cycle.

- How long to use it

Your doctor or nurse will advise you on which days you should use it.

- If you forget to use it

If you missed an injection, do not 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.

- If you use too much (overdose)

Immediately contact your doctor if you are concerned that you have given yourself too much or someone else has injected themselves with Pergoveris. The effects of an overdose of Pergoveris are unknown, nevertheless one could expect ovarian hyperstimulation syndrome (OHSS) to occur. However, this will only occur if hCG is administered. If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using Pergoveris

- Things you must do

Tell your doctor immediately if you become pregnant while using Pergoveris

Tell your doctor immediately if:

- Your skin becomes fragile and easily blistered, especially skin that has been frequently exposed to sunlight
- You have stomach, arm or leg pain.

Before starting any new medicine, tell your doctor and pharmacist that you are using Pergoveris.

- Thing you must not do

Do not use Pergoveris to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop using Pergoveris without first checking with your doctor.

Do not change the dose unless your doctor tells you to.

Do not use in children and adolescents below 18 years old.

- Things to be careful of

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

Side effects

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

The most commonly reported adverse reactions are headache, ovarian cysts and local injection site reactions (e.g. pain, redness, bruising, swelling and/or irritation at the site of injection).

Mild or moderate ovarian hyperstimulation syndrome (OHSS) has been commonly reported. If this happens, your doctor will need to examine you as soon as possible.

Very Common:

- Sacs of fluid within the ovaries (ovarian cysts)
- Headache
- Local reactions at the injection site

such as pain, itching, bruising, swelling or irritation

Common:

- Diarrhoea
- Breast pain
- Feeling sick or vomiting
- Abdominal or pelvic pain
- Abdominal cramp or bloating
- Mild or moderate ovarian hyperstimulation syndrome (OHSS)

If you get any side effects, talk to your doctor or pharmacist. Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients. Do not be alarmed by this list of possible side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Pergoveris

- Storage

Do not store above 25°C.

Store in the original package in order to protect from light.

Keep it where children cannot reach it.

- Disposal

For immediate and single use following first opening and reconstitution.

Any unused medicinal product or waste material should be disposed off in accordance with local requirements.

Product Description

- What it looks like

Powder: 3 ml vials (Type I glass) with a stopper (bromobutyl rubber) and aluminium flip-off cap.

1 vial contains 11 micrograms r-hFSH and 3 micrograms r-hLH.

Solvent: 3 ml vials (Type I glass) with a Teflon coated rubber stopper and aluminium flip-off cap.

1 vial of solvent contains 1 ml of water for injections.

Pack size: 1, 3 and 10's
Not all pack sizes are marketed

- Ingredients

Active ingredient: Follitropin alfa and lutropin alfa

Inactive ingredient:

Sucrose, Polysorbate 20, Methionine, Disodium phosphate dehydrate, Sodium dihydrogen phosphate monohydrate, Phosphoric acid, concentrated (for pH adjustment), Sodium hydroxide (for pH adjustment), water for injections

- MAL Number:

MAL20102081AZ

Manufacturer

Merck Serono SA
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Product Registration Holder

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