

PERGOVERIS®

Follitropin alfa (rch)/Lutropin alfa (rch) Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PERGOVERIS.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using PERGOVERIS against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this information with your medicine.

You may need to read it again later.

What PERGOVERIS is used for

PERGOVERIS is a medicine containing follitropin alfa, a recombinant follicle stimulating hormone (FSH) and lutropin alfa, a recombinant luteinising hormone (LH), which are essentially similar to the hormones found naturally in humans, but they are made by means of biotechnology. They belong to the family of hormones called gonadotrophins, which are involved in the normal control of reproduction.

PERGOVERIS is for the treatment of women who have been shown to produce very low levels of some of the hormones involved in the natural reproductive cycle. PERGOVERIS is used to bring about the development of a single mature follicle. Follicles are structures in the ovaries that mature the eggs (ova). Once adequate follicular development is achieved, a single injectable dose of human chorionic gonadotrophins (hCG) is given, which leads to the release of an egg from the follicle (ovulation).

Ask your doctor if you have any questions about why PERGOVERIS has been prescribed for you.

You doctor may have prescribed it for another reason.

PERGOVERIS is available only on a doctor's prescription.

PERGOVERIS is not habit-forming.

Before you are given PERGOVERIS

When you must not use it

Do not use PERGOVERIS if:

- you have a history of allergy to gonadotrophins or to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use PERGOVERIS if:

- you are pregnant
- you are breastfeeding
- your ovaries are enlarged
- you have an unexplained ovarian cyst
- you have unexplained vaginal or uterine bleeding
- you have cancer of the ovaries, uterus or breasts
- you have tumours of the pituitary gland or hypothalamus.

If you are not certain whether these conditions apply to you, or you are worried about anything on this list, tell your doctor.

Do not use this medicine after the expiry date (month/year) on the packaging has passed, or if the packaging is torn or shows signs of tampering.

If your medicine has expired or is damaged, return it to your pharmacist or clinic for disposal.

If you are not sure whether you should start using PERGOVERIS, talk to your doctor.

Before you start to use it

Your doctor will assess you and your partner's infertility. This may include tests for other medical conditions, which may interfere with your ability to become pregnant. If necessary, other medical conditions may be treated before starting infertility treatments including PERGOVERIS.

Tell your doctor if you are breastfeeding.

PERGOVERIS should not be used while you are breastfeeding.

Tell your doctor if you have any allergies to any foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have had any medical conditions, especially the following:

- premature menopause
- disorders of the thyroid gland
- disorders of the adrenal glands
- high prolactin levels in the blood
- fibroid tumours in your uterus which would make pregnancy impossible
- if you have been through menopause
- kidney disease
- liver disease
- you or your family have increased risk factors for developing blood clots, e.g. stroke, heart attacks.
- porphyria or a family history of porphyria.

Treatment with PERGOVERIS may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries over-react to the hormonal treatment and become larger.

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by using ultrasound and blood tests to help determine if you are likely to develop OHSS.

If necessary, your doctor will delay or cancel your PERGOVERIS injection. You may also be advised to refrain

from sexual intercourse or use barrier methods until the end of the cycle if this occurs.

Compared to natural conception, the frequency of multiple pregnancies and births is increased in patients receiving treatments that stimulate follicle growth for ovulation induction. The majority of these are twins. Your doctor will monitor your ovarian response to minimise the chance of multiple pregnancies, because of the greater risks they carry for mothers and babies. However, this risk can be minimised by using the recommended dose and time of injections.

Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing treatments to stimulate follicle growth for ovulation induction.

There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedures. An effect of medicines used to induce ovulation has not been excluded.

Talk to your doctor about any concerns you may have before undergoing treatment or before you start using PERGOVERIS.

Taking other medicines

Tell your doctor if you are taking any other medicines:

- all prescription medicines

- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while using PERGOVERIS.

How PERGOVERIS is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Treatment with PERGOVERIS should be started under the supervision of a specialist doctor experienced in fertility treatment.

PERGOVERIS is given as a course of daily injections. You should have your injection at the same time each day.

PERGOVERIS should not be given in the same injection with other medicines. If needed, PERGOVERIS solution for injection may be administered along with follitropin alfa as separate injections.

Do not use PERGOVERIS on anyone else.

It is for your use only.

How much to inject

Your treatment should be tailored according to your individual response.

Your doctor will tell you how much PERGOVERIS to use and when to inject it.

It is usually recommended that your treatment with PERGOVERIS starts with 150 IU of follitropin alfa/75 IU of lutropin alfa once a day.

If needed, your doctor may increase your dose of follitropin alfa by 37.5 - 75 IU, preferably at 7-14 day intervals.

How to inject

PERGOVERIS is given as a subcutaneous (under your skin) injection in the lower abdominal area or thigh, each day for up to 3 weeks.

Your doctor may decide to extend the treatment to up to 5 weeks.

PERGOVERIS is intended to be injected by you or by your partner.

Alternatively, your doctor or a nurse may give you these injections.

If your doctor or nurse decides you can give the injections yourself, the doctor or a nurse will teach you the injection technique.

Do not self-inject until you are sure of how to do it.

Read the Instructions for Use provided in the pack carefully before commencing injections.

Your partner may be trained to give the injection at home.

Where to inject

PERGOVERIS is usually given in the lower abdominal area (except around the navel and waistline) or the front of your thigh. The injection site should be changed daily to lessen possible injection site reactions

Do not inject into any areas in which you feel lumps, firm knots, depressions, pain or discolouration.

Talk to your doctor if you find anything unusual when injecting.

If you forget to inject PERGOVERIS

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject a double dose on any day.

Ask your doctor if you are not sure what to do or have trouble remembering to inject your medicine.

If you injected too much

Immediately contact your doctor or the Poisons Information Centre (telephone 131 126) if you are concerned that you have given yourself too much or someone else has injected themselves with PERGOVERIS.

While you are using PERGOVERIS

Your doctor will carefully monitor your response using ultrasound and blood tests before and during treatment with PERGOVERIS.

Things you must do

See your doctor regularly.

Your doctor will monitor you closely throughout your treatment.

Tell your doctor immediately if you become pregnant while using PERGOVERIS.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using PERGOVERIS.

If you plan to have surgery, tell your doctor or dentist that you are using PERGOVERIS.

Tell all the doctors, dentists and pharmacists who are treating you that you are using PERGOVERIS.

Things you must not do

If you are self-injecting do not:

- Stop using PERGOVERIS without telling your doctor.
- Change the dose unless your doctor tells you to. Changing your dose without advising your doctor can increase your

risk of unwanted side effects or prevent the medicine from working properly.

- Give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how PERGOVERIS affects you.

Side effects

Tell your doctor as soon as possible if you do not feel well while using PERGOVERIS.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately, or go to the Accident and Emergency section of your nearest hospital if you experience any of the following:

- signs of allergic reactions, including swelling of the face, lips, tongue or other parts of the body; shortness of breath,

wheezing or difficulty breathing; severe skin rash, itching or hives

- vaginal bleeding
- inflammation, swelling or pain in your legs
- signs of severe OHSS such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amounts of urine and shortness of breath
- warning signs of stroke or heart attack
- warning signs of blood clots (such as pain, warmth, redness, numbness or tingling in arm or leg).

Tell your doctor if you notice any of the following and they worry you:

- headache, dizziness
- nausea, vomiting, diarrhoea, abdominal discomfort, abdominal distension, abdominal pain
- ovarian cysts, ovarian enlargement, breast pain, pelvic pain
- local reactions at the injection site, such as bruising, pain, redness, itching or swelling.

Ectopic pregnancy (embryo implanted outside the womb) may occur, especially in women with a history of prior tubal disease.

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.

After using PERGOVERIS

Storage

Prior to using, store PERGOVERIS in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

After the first injection, the pen may be stored below 25°C for a maximum of 28 days with the cap on, in order to protect the product from light.

Do not use PERGOVERIS if the solution contains particles or is not clear.

Do not use the product after the expiry date printed on the label.

Do not use PERGOVERIS if you notice any visible signs of deterioration or damage to the container.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If you are self-injecting, you should discard all sharps into a disposal unit.

If you have any PERGOVERIS that has expired or is left over from your treatment, refer this to your clinic.

Product description

What it looks like

PERGOVERIS solution for injection contains sterile, clear, colourless to slightly yellow solution for injection in a cartridge, pre-assembled in a disposable pen.

PERGOVERIS solution for injection is available in the following presentations and pack sizes*:

- 300 IU of follitropin alfa and 150 IU of lutropin alfa in 0.48 mL. The pack contains 1 cartridge of solution for injection pre-assembled in a disposable pen and 5 needles for administration.
- 450 IU of follitropin alfa and 225 IU of lutropin alfa in 0.72 mL.

The pack contains 1 cartridge of solution for injection pre-assembled in a disposable pen and 7 needles for administration.

- 900 IU of follitropin alfa and 450 IU of lutropin alfa in 1.44 mL.

The pack contains 1 cartridge of solution for injection pre-assembled in a disposable pen and 14 needles for administration.

* Not all presentations and pack sizes may be marketed.

Ingredients

Active ingredient:

- Follitropin alfa (rch)
- Lutropin alfa (rch)

Inactive ingredients:

- Poloxamer
- Arginine hydrochloride
- Phenol
- Dibasic sodium phosphate dihydrate
- Monobasic sodium phosphate monohydrate
- Methionine
- Sucrose
- Phosphoric acid

- Sodium hydroxide
- Water for injections

Supplier

PERGOVERIS solution for injection is supplied in Australia by:

Merck Serono Australia Pty Ltd

3-4/25 Frenchs Forest Road

Frenchs Forest NSW 2086

E-mail: medinfo.australia@merckgroup.com

For enquiries call: 1800 633 463

Australian Registration Number

PERGOVERIS follitropin alfa (rch)/lutropin alfa (rch) 300 IU/150 IU in 0.48 mL solution for injection cartridge pre-assembled in a pen: AUST R 288927

PERGOVERIS follitropin alfa (rch)/lutropin alfa (rch) 450 IU/225 IU in 0.72 mL solution for injection cartridge pre-assembled in a pen: AUST R 288928

PERGOVERIS follitropin alfa (rch)/lutropin alfa (rch) 900 IU/450 IU in 1.44 mL solution for injection cartridge pre-assembled in a pen: AUST R 288929

Date of preparation

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