

PERGOVERIS®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PERGOVERIS?

PERGOVERIS contains the active ingredients follitropin alfa (recombinant follicle stimulating hormone (FSH)) and lutropin alfa (recombinant luteinising hormone (LH)). PERGOVERIS is used for the stimulation of follicular development in women with severe LH and FSH deficiency.

For more information, see Section [1. Why am I using PERGOVERIS?](#) in the full CMI.

2. What should I know before I use PERGOVERIS?

Do not use if you have ever had an allergic reaction to PERGOVERIS or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PERGOVERIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PERGOVERIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PERGOVERIS?

- It is usually recommended that your treatment with PERGOVERIS starts with 150 IU of follitropin alfa/75 IU of lutropin alfa once a day as a subcutaneous (under the skin) injection in your lower abdominal area or thigh. Your doctor will tell you how much PERGOVERIS to use and when to inject it. Your treatment should be tailored according to your individual response.
- Follow all directions given to you by your doctor or pharmacist carefully, including the Instructions for Use provided in the pack.

More instructions can be found in Section [4. How do I use PERGOVERIS?](#) in the full CMI.

5. What should I know while using PERGOVERIS?

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using PERGOVERIS. ● Tell your doctor if you become pregnant while using PERGOVERIS
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly without telling your doctor. ● Change the dose unless your doctor tells you to. ● Give this medicine to anyone else, even if their symptoms seem similar to yours.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how PERGOVERIS affects you.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Prior to use, 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.

- Keep this medicine where children cannot reach it.
- Do not use the medicine after the expiry date on the label.

For more information, see Section [5. What should I know while using PERGOVERIS?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor if you experience any side effects. Most common side effects include injection site reactions, headache, dizziness, ovarian enlargement or cysts.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PERGOVERIS®

Active ingredient(s): *follitropin alfa (rch) and lutropin alfa (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PERGOVERIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PERGOVERIS.**

Where to find information in this leaflet:

- [1. Why am I using PERGOVERIS?](#)
- [2. What should I know before I use PERGOVERIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PERGOVERIS?](#)
- [5. What should I know while using PERGOVERIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PERGOVERIS?

PERGOVERIS contains the active ingredient **follitropin alfa**, a recombinant follicle stimulating hormone (FSH) and **lutropin alfa**, a recombinant luteinising hormone (LH). These hormones 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 used for the stimulation of follicular development in women with severe LH and FSH deficiency.

2. What should I know before I use PERGOVERIS?

Warnings

Do not use PERGOVERIS if:

- you are allergic to gonadotrophins, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant
- you are breastfeeding
- you have an unexplained ovarian enlargement or 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 if you are worried about anything on the list, tell your doctor.

Check with your doctor if you:

- take any medicines for any other condition
- have or have had any other medical conditions, such as:
 - premature menopause
 - disorders of thyroid glands
 - disorders of the adrenal glands
 - high prolactin levels in the blood
 - fibroid tumours in your uterus which would make pregnancy impossible
 - 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.

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 with PERGOVERIS.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use PERGOVERIS if you are pregnant or breastfeeding.

Check with your doctor if you are pregnant while using PERGOVERIS.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Compared to natural conception, the frequency of multiple pregnancies and births is increased.

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 treatment to stimulate follicular growth.

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 with PERGOVERIS.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PERGOVERIS.

4. How do I use PERGOVERIS?

How much to use

- It is usually recommended that your treatment with PERGOVERIS starts with 150 IU of follitropin alfa/75 IU of follitropin alfa once a day.
- Your treatment should be tailored according to your individual response. Your doctor will tell you how much PERGOVERIS to use.

When to use PERGOVERIS

- Your doctor will tell you when to take PERGOVERIS.
- PERGOVERIS is given as a course of daily injections. You should have your injection at the same time each day.

How to use PERGOVERIS

- PERGOVERIS should be injected daily under the skin (subcutaneous) in the lower abdominal area or thigh (except around the navel and waistline).
- The injection site should be changed daily to lessen possible injection site reactions.
- Before using PERGOVERIS, your doctor or nurse can teach you the injection technique.
- Read the Instructions for Use provided in the pack carefully before commencing injections.

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

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

If you forget to use PERGOVERIS

PERGOVERIS should be used regularly at the same time each day. If you miss your dose at the usual time, contact your doctor or nurse immediately for advice.

If you use too much PERGOVERIS

If you think that you have used too much PERGOVERIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PERGOVERIS?

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

Remind any doctor, dentist or pharmacist you visit that you are using PERGOVERIS.

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor.
- Do not change the dose unless your doctor tells you to.
- Give this medicine to anyone else even if they have the same condition as you.

Ovarian Hyperstimulation Syndrome (OHSS)

Treatment with PERGOVERIS may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries overreact 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PERGOVERIS affects you.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• Injection site reactions, such as bruising, pain, redness, itching or swelling• Headache, dizziness• Ovarian enlargement or cysts, breast pain, pelvic pain• Nausea, vomiting, diarrhoea, abdominal discomfort, distension or pain• Ectopic pregnancy (embryo implanted outside the womb) may occur.	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reactions (very rare): <ul style="list-style-type: none">• severe skin rash, itching or hives	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 <p>Ovarian Hyperstimulation Syndrome (OHSS):</p> <ul style="list-style-type: none"> ● Signs of OHSS: <ul style="list-style-type: none"> ○ lower abdominal pain, discomfort or swelling ○ nausea, vomiting, diarrhoea ○ pelvic pain <p>Signs of severe OHSS include rapid weight gain, low urine output and shortness of breath.</p> <p>Very rarely, blood clot (thromboembolism) associated with severe OHSS may occur. Signs of blood clot include pain, warmth, redness, numbness or tingling in</p>	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
arm or legs, warning signs of stroke or heart attack.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PERGOVERIS contains

Active ingredient (main ingredient)	follitropin alfa (rch) and lutropin alfa (rch)
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<p>Other ingredients (inactive ingredients)</p>	<p>poloxamer arginine hydrochloride phenol dibasic sodium phosphate dihydrate monobasic sodium phosphate monohydrate methionine sucrose phosphoric acid sodium hydroxide water for injections</p>
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Do not take this medicine if you are allergic to any of these ingredients.

What PERGOVERIS 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 (AUST R 288927).

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 (AUST R 288928).

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 (AUST R 288929).

* Not all presentations and pack sizes may be marketed.

Who distributes PERGOVERIS

PERGOVERIS solution for injection is supplied in Australia by:

Merck Healthcare Pty Ltd

Suite 1, Level 1, Building B

11 Talavera Road

Macquarie Park NSW 2113

E-mail: medinfo.australia@merckgroup.com

For enquiries call: 1800 633 463

This leaflet was prepared in March 2023.