

Ganirelix Lupin

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 Ganirelix Lupin?

Ganirelix Lupin is used together with other medications to regulate hormone response in women undergoing Assisted Reproductive Technology (ART) such as *in vitro* fertilisation (IVF). It works by preventing women from ovulating (releasing an egg from the ovary) too soon during stimulation of their ovaries to produce a mature egg.

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

2. What should I know before I use Ganirelix Lupin?

Do not use if you have ever had an allergic reaction to ganirelix 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, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Ganirelix Lupin 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 Ganirelix Lupin?

- Your doctor will decide the dose suitable for you based on your condition and response.

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

5. What should I know while using Ganirelix Lupin?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Ganirelix Lupin.Tell your doctor if other medications are prescribed to you during the course of therapy with Ganirelix Lupin.Contact your doctor immediately if you have severe pelvic pain, nausea and vomiting, and weight gain.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly without telling your doctor.Do not change the dose unless your doctor tells you to.Do not use this medicine if you have moderate to severe kidney or liver disease.Do not use this medicine if you are pregnant or breastfeeding.
Driving or using machines	<ul style="list-style-type: none">No effects on ability to drive and use of machines have been observed.
Looking after your medicine	<ul style="list-style-type: none">Keep Ganirelix Lupin below 25°C. Do not put it in the freezer as the syringe may break.Keep the syringe in the outer carton to protect it from light.

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

6. Are there any side effects?

The common side effects are: redness; pain or swelling at injection site; headache; nausea; tiredness.

The serious side effects are: shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest; swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (also called as angioedema and/or anaphylaxis), or other parts of the body; rash, itching, hives (urticaria); or flushed, red skin.

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.

Ganirelix Lupin

Active ingredient(s): ganirelix

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ganirelix Lupin. **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 Ganirelix Lupin.**

Where to find information in this leaflet:

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

1. Why am I using Ganirelix Lupin?

Ganirelix Lupin contains the active ingredient ganirelix. Ganirelix Lupin works by preventing women from ovulating (releasing an egg from the ovary) too soon during stimulation of their ovaries to produce a mature egg.

Ganirelix Lupin is used together with other medications to regulate hormone response in women undergoing Assisted Reproductive Technology (ART) such as *in vitro* fertilisation (IVF).

2. What should I know before I use Ganirelix Lupin?

Warnings

Do not use Ganirelix Lupin if:

- you are allergic (hypersensitive) to ganirelix or to any other components of Ganirelix Lupin, including the ingredients listed at the end of this leaflet and/or synthetic rubber.
Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines.
- you are pregnant.
- you are breastfeeding.
- you have moderate to severe kidney or liver disease.
- the solution is not clear or colourless.
- the expiry date on the pack has passed.
- the package shows any signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, substances such as foods, preservatives, or dyes.
- are currently experiencing allergic symptoms.
- take any medicines for any other condition.
- have any other medical conditions.

Compared to natural conception, the frequency of multiple pregnancies and births is increased in patients undergoing assisted reproductive techniques. Discuss the risk of multiple pregnancies and births with your doctor.

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

Ganirelix Lupin is not to be used during pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant.

Ganirelix Lupin should not be used by breastfeeding women. It is not known whether ganirelix is excreted into animal or human breast milk.

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

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 Ganirelix Lupin.

4. How do I use Ganirelix Lupin?

How much to use

- The usual dose is the contents of one pre-filled syringe of Ganirelix Lupin once a day on specific days of the menstrual cycle. Your doctor will tell you when to inject Ganirelix Lupin.
- You may notice air bubbles in the pre-filled syringe. This is expected, and removal of the air bubbles is not needed.
- Follow the instructions provided and use Ganirelix Lupin until your doctor tells you to stop.

When to use Ganirelix Lupin

- Ganirelix Lupin should be injected subcutaneously (under the skin) once daily, starting from day 5 or day 6 of follicle stimulating hormone (FSH) administration depending on the level of ovarian response.

How to use Ganirelix Lupin

- Treatment with Ganirelix Lupin should be started under the supervision of a fertility specialist.
- Ganirelix Lupin is given as a subcutaneous (under the skin) injection in the thigh or stomach/abdomen.
- The injection site should be changed every day to lessen possible injection site reactions.
- If your doctor or nurse decides you can give the injections yourself, they will teach you the injection technique.

Do not attempt self-injection until you are sure of how to do it. Follow all instructions given to you by your doctor or nurse carefully.

Follow these steps for self-injection:

1. Prepare the injection site:

- Wash your hands thoroughly with soap and water.
- Swab the injection site with a disinfectant to remove any surface bacteria. Clean about 5 cm around the point where the needle will go in.
- Let the disinfectant dry for at least one minute before proceeding.

2. Open the outer pack and plastic container inside:

- While waiting for the disinfectant to dry, open the Ganirelix Lupin pack and remove the plastic container.
- Carefully open the plastic container and remove the Ganirelix Lupin syringe.
- You will see the needle is already attached, covered by a black needle shield.

3. Prepare the syringe for injection:

- Remove the needle shield and discard it in a Sharps Container.
- You are now ready to inject Ganirelix Lupin.

4. Inserting the needle and injecting:

- Ganirelix Lupin is injected in either the thigh or the stomach/abdomen, usually near the navel.
- Pinch up a large bit of skin between your finger and thumb.
- Insert the needle at the base of the pinched-up skin at an angle of 45 degrees to 90 degrees to the skin surface.
- Gently draw back on the plunger to see if the needle is inserted correctly.
- If any blood appears in the syringe, the needle is not inserted correctly so do not inject Ganirelix Lupin. Remove the needle, cover the injection site with a sterile swab and dispose of the syringe in a Sharps Container. Start again with a new syringe.
- If the needle has been inserted correctly, press down on the plunger slowly and steadily until all the solution has been injected.
- Vary the injection site each time to minimise local irritation.

5. Removing the needle:

- Pull the needle out of the skin quickly and apply pressure to the site with a swab containing disinfectant.
- Dispose of the syringe (with the attached needle) in a Sharps Container.
- Use the syringe only once and then dispose of it in a Sharps Container.

If you forget to use Ganirelix Lupin

If you forget an injection, contact your doctor or IVF clinic immediately for advice.

Do not inject a double dose to make up for the forgotten dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you use too much Ganirelix Lupin

If you think that you have used too much Ganirelix Lupin, 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 Ganirelix Lupin?

Things you should do

- **Keep all your doctor's appointments so that your progress can be checked.**
Your doctor will want to follow the developing eggs inside the ovaries by doing an ultrasound examination and measuring hormones in your blood.
- Remind any doctor, dentist or pharmacist you visit that you are using Ganirelix Lupin.
- Tell the hospital doctor that you are using Ganirelix Lupin if you need to have an operation or go to hospital in an emergency.
If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Ganirelix Lupin.

Call your doctor straight away if you:

- **have severe pelvic pain, nausea, vomiting and weight gain.** These are early warning signs of Ovarian Hyperstimulation Syndrome (OHSS). Other symptoms of OHSS can include:
 - indigestion;
 - diarrhoea;
 - shortness of breath;
 - reduced amounts of urine;
 - painful breasts.

OHSS is a possible complication of hormonal stimulation of the ovaries.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using Ganirelix Lupin.

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. Changing your dose without telling your doctor can increase your risk of unwanted side effects or can prevent the drug from working properly.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints.

Driving or using machines

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

No effects on ability to drive or use of machines have been observed.

Looking after your medicine

- Store below 25°C in the original package.
- Do not put in the freezer as the syringe may break.
- Keep the syringe in the outer carton to protect it from light.

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

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.

Alternatively, dispose of your Ganirelix Lupin syringe and needle safely into a Sharps Container.

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.

Less serious side effects

Less serious side effects	What to do
<p>Skin-related:</p> <ul style="list-style-type: none"> • Redness, pain or swelling at injection site. <p>Pain-related:</p> <ul style="list-style-type: none"> • Headache. <p>Digestive track-related:</p> <ul style="list-style-type: none"> • Nausea. <p>Other:</p> <ul style="list-style-type: none"> • Tiredness. 	<p>Speak to your doctor or IVF clinic if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Respiratory-related:</p> <ul style="list-style-type: none"> • Shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest. <p>Hypersensitivity-related:</p> <ul style="list-style-type: none"> • Swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (also called as angioedema and/or anaphylaxis), or other parts of the body. • Rash, itching, hives (urticaria), flushing and red skin. 	<p>Call your doctor or IVF clinic straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Other side effects

Other side effects are known to occur with Assisted reproductive Technology (ART) procedures. These may include:

- Ovarian Hyperstimulation Syndrome or OHSS (enlargement of the ovaries). Since overstimulation can occur rapidly you must contact your doctor if you experience any of the following:
 - pain in the abdomen or pelvis, indigestion, nausea, vomiting, weight gain, shortness of breath, reduced amounts of urine, diarrhoea and painful breasts.
- vaginal bleeding.
- miscarriage.
- ectopic pregnancy. The incidence of ectopic pregnancies (embryo implanted outside the womb) may be increased in women undergoing ART. Your doctor will perform an ultrasound scan early during

pregnancy to confirm that a pregnancy is intrauterine (in the womb).

These side effects are probably unrelated to treatment with Ganirelix Lupin.

The incidence of congenital malformations (a physical defect present in a baby at birth) after ART may be slightly higher than after spontaneous conceptions. The slightly higher incidence is thought to be related amongst other factors or characteristics of the patients undergoing fertility treatment (eg. age of the female, sperm characteristics, etc.) and to the higher incidence of multiple gestations after ART. The incidence of congenital malformations after ART using Ganirelix Lupin is not different from that after using other GnRH analogues during ART.

The needle shield of Ganirelix Lupin contains synthetic rubber which comes in contact with the product and may cause allergic reactions.

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 Ganirelix Lupin contains

Active ingredient (main ingredient)	Ganirelix
Other ingredients (inactive ingredients)	Glacial acetic acid Mannitol Water for injections
Potential allergens	Synthetic rubber

Do not take this medicine if you are allergic to any of these ingredients.

What Ganirelix Lupin looks like

Ganirelix Lupin is supplied as a clear, colourless solution in a single use, pre-filled syringe with a fixed needle closed by a needle shield (AUST R 442691).

Who distributes Ganirelix Lupin

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

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This leaflet was prepared in February 2026.