

GANIRELIX THERAMEX®

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 Theramex?

Ganirelix Theramex contains the active ingredient ganirelix (as acetate). Ganirelix Theramex is used together with other medications to regulate hormone response in women undergoing Assisted Reproductive Technology such as in vitro fertilisation (IVF).

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

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

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 Theramex?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ganirelix Theramex 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 Theramex?

- Treatment with Ganirelix Theramex should be started under the supervision of a fertility specialist
- Ganirelix Theramex is given as a subcutaneous (under the skin) injection in the thigh or stomach
- The usual dose is the contents of one pre-filled syringe of Ganirelix Theramex once a day on specific days of the menstrual cycle.

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

5. What should I know while using Ganirelix Theramex?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Ganirelix Theramex.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without telling your doctor.• Do not change the dose unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• No effects on ability to drive and use machines have been observed.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol is not expected to interact with Ganirelix Theramex. If you drink alcohol, talk to your doctor about the possible side effects of taking alcohol with this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store Ganirelix Theramex in a cool dry place, out of direct light, where the temperature is below 30°C. Do not freeze as the syringe may break.• Keep Ganirelix Theramex in the original packaging, in a safe place, away from children.

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

6. Are there any side effects?

The most common side effects are skin reactions at the site of injection. Other common side effects include headache and nausea and tiredness. Serious side effects include shortness of breath, vaginal bleeding, miscarriage or ectopic pregnancy.

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 THERAMEX®

Active ingredient(s): ganirelix (as acetate) 250 micrograms in 0.5 milliliters

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Ganirelix Theramex?

Ganirelix Theramex contains the active ingredient ganirelix (as acetate). Ganirelix Theramex 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 Theramex is used together with other medications to regulate hormone response in women undergoing Assisted Reproductive Technology such as in vitro fertilisation (IVF).

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

Do not use Ganirelix Theramex if:

- you are allergic to ganirelix, 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 moderate to severe kidney or liver disease.
- the solution is not clear and colourless.
- the expiry date on the pack has passed.
- the package shows any signs of tampering.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition.

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

Talk with your doctor if you are pregnant or if you are breastfeeding.

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.

4. How do I use Ganirelix Theramex?

How much to use

- Treatment with Ganirelix Theramex should be started under the supervision of a fertility specialist.
- The usual dose is the contents of one pre-filled syringe of Ganirelix Theramex once a day on specific days of the menstrual cycle.

When to use Ganirelix Theramex

- Your doctor will tell you when to inject Ganirelix Theramex.

How to use Ganirelix Theramex

- Ganirelix Theramex is given as a subcutaneous (under the skin) injection in the thigh or stomach.
- 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.
- The injection site should be changed every day to lessen possible injection site reactions.
- Follow all instructions given to you by your doctor or nurse carefully. Follow these steps:

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 Theramex pack and remove the plastic container. Carefully open the plastic container and remove the Ganirelix Theramex syringe. You will see the needle is already attached, covered by a grey needle shield.

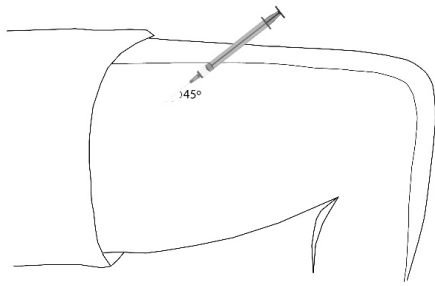
3. Prepare the syringe for injection

Remove needle shield and discard it in a sharps-disposable bin. You are now ready to inject Ganirelix Theramex.

4. Inserting the needle and injecting

Ganirelix Theramex is injected in either the thigh or the 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

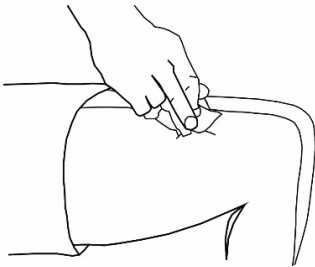
blood appears in the syringe, the needle is not inserted correctly so do not inject Theramex Ganirelix.



Remove the needle, cover the injection site with a sterile swab and dispose of the syringe in a sharps-disposable container. Start again with a new syringe. If the needle has been inserted correctly, depress 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 the Sharps Container.



If you forget to use Ganirelix Theramex

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 you use too much Ganirelix Theramex

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26)
- contact your doctor, or IVF clinic 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 Theramex?

Things you should do

Call your doctor straight away if you:

- Have severe pelvic pain, nausea and vomiting and weight gain. There 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 breast

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

Keep all of 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 Theramex.

Tell the hospital doctor that you are using Ganirelix Theramex 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 Theramex.

Things you should not do

If you are self-injecting

- Do not stop using Ganirelix Theramex 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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol is not expected to interact with Ganirelix Theramex. If you drink alcohol, talk to your doctor about the possible side effects of taking alcohol with this medicine.

Looking after your medicine

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

Store Ganirelix Theramex in a cool dry place below 30°C 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.

Do not freeze as the syringe may break.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Dispose of your Ganirelix Theramex syringe and needle safely into a yellow plastic Sharps Container.

If your doctor tells you to stop using Ganirelix Theramex or the expiry date has passed, ask your pharmacist or IVF clinic what to do with any Ganirelix Theramex that is left over.

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
<ul style="list-style-type: none">redness, pain or swelling at injection site. Usually, these symptoms disappear within a few hours after injection.headachenauseatiredness	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">shortness of breath, wheezing, difficulty breathing or a tight feeling in your chestswelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (angioedema and/or anaphylaxis), or other parts of the bodyrash, itching, hives (urticaria) or flushed, red skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Other side effects are known to occur with Assisted Reproductive Technology (ART) procedures.

These may include:

- Ovarian Hyperstimulation Syndrome. 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 Theramex.

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 to characteristics of the patients undergoing fertility treatment (e.g., age of the female, sperm characteristics) and to the higher incidence of multiple gestations after ART. The incidence of congenital malformations after ART using

Ganirelix Theramex is not different from that after using other GnRH analogues in the course of ART.

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 Theramex contains

Active ingredient (main ingredient)	250 micrograms of ganirelix (as acetate)
Other ingredients (inactive ingredients)	Glacial acetic acid Mannitol Water for injections

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

What Ganirelix Theramex looks like

Ganirelix Theramex is a clear colourless solution. It comes in a pre-filled syringe with fixed needle closed by a needle shield of elastomeric (latex free) rubber. Ganirelix Theramex is available in packs of 1 or 5 pre-filled syringes (Aust R 384707).

Who distributes Ganirelix Theramex

Theramex Australia Pty Ltd
Level 22, 60 Margaret Street,
Sydney NSW 2000

1800 THERAMEX or 1800 843 726

This leaflet was prepared in February 2022.