

ORGALUTRAN®

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 ORGALUTRAN?

ORGALUTRAN contains the active ingredient ganirelix (as acetate). ORGALUTRAN is used together with other medications to regulate hormone response in women undergoing fertility treatments such as in vitro fertilisation (IVF).

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

2. What should I know before I use ORGALUTRAN?

Do not use if you have ever had an allergic reaction to ganirelix (as acetate) 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 ORGALUTRAN?](#) in the full CMI.

3. What if I am taking other medicines?

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

See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ORGALUTRAN?

- Treatment should be initiated under the supervision of a fertility specialist.
- ORGALUTRAN is given as a subcutaneous (under the skin) injection in the thigh or stomach, on specific days of your menstrual cycle. Your doctor will tell you when to inject ORGALUTRAN.

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

5. What should I know while using ORGALUTRAN?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ORGALUTRAN.• Keep this leaflet. You may need to read it again. |
| Things you should not do | <ul style="list-style-type: none">• Do not attempt self-injection until you are sure how to do it.• Do not stop using this medicine suddenly 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 |
| Looking after your medicine | <ul style="list-style-type: none">• Keep ORGALUTRAN at room temperature below 30°C. Do not freeze.• Keep ORGALUTRAN in a safe place away from the sight and reach of children.• Keep the syringe in the outer carton to protect from light. |

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

6. Are there any side effects?

Common side effects include local skin reactions at the site of injection. Serious side effects include allergic reactions (i.e. hives, swelling of the face, difficulty breathing, etc.), vaginal bleeding, miscarriage, ectopic pregnancy and ovarian hyperstimulation syndrome (OHSS).

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.

ORGALUTRAN®

Active ingredient(s): ganirelix (as acetate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ORGALUTRAN. **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 ORGALUTRAN.**

Where to find information in this leaflet:

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

1. Why am I using ORGALUTRAN?

ORGALUTRAN contains the active ingredient ganirelix (as acetate), which inhibits actions of the natural gonadotropin releasing hormone (GnRH).

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

ORGALUTRAN works by preventing women from ovulating (releasing an egg from the ovary) too soon during stimulation of their ovaries to produce a mature egg.

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

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

2. What should I know before I use ORGALUTRAN?

Warnings

Do not use ORGALUTRAN if:

- you are allergic (hypersensitive) to ganirelix, or any other components of ORGALUTRAN, including the ingredients listed at the end of this leaflet.
- 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 and colourless
- the expiry date on the pack has passed
- the package shows any signs of tampering

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

Tell your doctor if:

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

Cases of allergic reactions, both generalised and local, including hives (urticaria), swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (angioedema and/or anaphylaxis) have been reported, as early as with the first dose. (See also Section [6. Are there any side effects?](#)). If you have an allergic reaction, stop taking ORGALUTRAN and seek immediate medical assistance.

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 ORGALUTRAN if you are pregnant or 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.

Do not mix ORGALUTRAN with any other medicines.

4. How do I use ORGALUTRAN?

Treatment with ORGALUTRAN should be started under the supervision of a fertility specialist.

ORGALUTRAN is given as a subcutaneous (under the skin) injection in the thigh or stomach.

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.

How much to inject

- The usual dose is the contents of one pre-filled syringe of ORGALUTRAN once a day on specific days of the menstrual cycle. Your doctor will tell you when to inject ORGALUTRAN.
- You may notice air bubbles in the pre-filled syringe. This is expected, and removal of the air bubbles is not needed.

How to use ORGALUTRAN

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 ORGALUTRAN pack and remove the plastic container. Carefully open the plastic container and remove the ORGALUTRAN 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 ORGALUTRAN.

4. Inserting the needle and injecting

ORGALUTRAN 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 ORGALUTRAN.

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.

How long to use ORGALUTRAN

Your doctor will tell you when to inject ORGALUTRAN and when to stop injecting it.

If you forget to use ORGALUTRAN

- 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 inject too much ORGALUTRAN

If you think that you have injected too much ORGALUTRAN, you may need urgent medical attention.

You should immediately:

- contact your doctor or IVF clinic, or
- phone the Poisons Information Centre (by calling 13 11 26) for Australia, or National Poisons Centre (telephone 0800 POISON or 0800 764 766) for New Zealand, 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 ORGALUTRAN?

Things you should do

Contact your doctor immediately if you have severe pelvic pain, nausea and 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 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.

Make sure that all doctors, dentists and pharmacists who are treating you know you are using ORGALUTRAN.

Tell the hospital doctor that you are using ORGALUTRAN 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 ORGALUTRAN.

Things you should not do

If you are self injecting:

- 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.

Things you should be careful of

- 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.

Driving or using machines

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

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

ORGALUTRAN is not addictive.

Looking after your medicine

- **Keep ORGALUTRAN at room temperature below 30°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.**
- **Keep ORGALUTRAN in a safe place away from the sight and reach of children.**
A locked cupboard at least one-and-a-half-metres above the ground is a good place to store medicines.
- Follow the instructions in the carton on how to take care of your medicine properly.

Store ORGALUTRAN 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.

Disposal

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

If your doctor tells you to stop using ORGALUTRAN or the expiry date has passed, ask your pharmacist or IVF clinic what to do with any ORGALUTRAN 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.• headache• nausea• tiredness | 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 chest• swelling 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 body• rash, itching, hives (urticaria) or flushed, red skin <p>This list includes very serious side effects that have been observed, as early as with the first dose. You may need urgent medical attention or hospitalisation. These side effects are rare.</p> | 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 ORGALUTRAN.

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

Tell your doctor if you notice anything that is making you feel unwell. Other side effects not listed above 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 ORGALUTRAN contains

| | |
|---|---|
| Active ingredient (main ingredient) | Ganirelix (as acetate) 250 microgram |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • Acetic acid • Mannitol • Water for injections |

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

What ORGALUTRAN looks like

ORGALUTRAN is a clear colourless solution. It comes in a pre-filled syringe with fixed needle closed by a needle shield.

ORGALUTRAN is available in packs of 1 or 5 pre-filled syringes (Aust R 74931).

Who distributes ORGALUTRAN

Organon Pharma Pty Ltd
Level 5, 66 King St
Sydney NSW 2000
Australia

Organon (New Zealand) Limited
Level 7, 36 Brandon Street
Wellington 6011
New Zealand

This leaflet was prepared in April 2025.