

Ganirelix-AFT

Ganirelix (as acetate) 250 micrograms in 0.5 millilitres

solution for injection

What is in this leaflet

Please read this leaflet carefully before you start using Ganirelix-AFT.

This leaflet answers some common questions about Ganirelix-AFT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Ganirelix-AFT against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Ganirelix-AFT is used for

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

Ganirelix-AFT 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.

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

Ganirelix-AFT is not addictive.

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

Before you use Ganirelix-AFT

When you must not use it

Do not use Ganirelix-AFT if:

- you are allergic (hypersensitive) to ganirelix or to any other components of Ganirelix-AFT, 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 Ganirelix-AFT, talk to your doctor.

Before you start to use it

Tell your doctor if:

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

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 Side Effects).

If you have an allergic reaction, stop taking Ganirelix-AFT and seek immediate medical assistance.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Ganirelix-AFT.

How to use Ganirelix-AFT

Treatment with Ganirelix-AFT should be started under the supervision of a fertility specialist.

Ganirelix-AFT 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 Ganirelix-AFT once a day on specific days of the menstrual cycle. Your doctor will tell you when to inject Ganirelix-AFT.

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 Ganirelix-AFT

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-AFT pack. You will see the needle is already attached, covered by a 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-AFT.

4. Inserting the needle and injecting

Ganirelix-AFT 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 Ganirelix-AFT. 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 take Ganirelix-AFT

Your doctor will tell you when to inject Ganirelix-AFT and when to stop injecting it.

If you forget to use Ganirelix-AFT

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.

While you are using Ganirelix-AFT

Things you must 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 breasts

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 Ganirelix-AFT.

Tell the hospital doctor that you are using Ganirelix-AFT 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-AFT.

Things you must not do

If you are self-injecting:

- do not stop using Ganirelix-AFT 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 to 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.

In case of overdose

If you inject too much (overdose)

Immediately contact your doctor or IVF clinic or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you have given yourself too much Ganirelix-AFT.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Ganirelix-AFT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

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

- redness, pain or swelling at injection site. Usually, these symptoms disappear within a few hours after injection.
- headache
- nausea
- tiredness

Tell your doctor immediately if you notice any of the following:

- 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

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.

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-AFT.

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

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Ganirelix-AFT

Storage

Keep Ganirelix-AFT 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.

Store 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.

Disposal

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

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

Product description

What it looks like

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

One box of Ganirelix-AFT contains one syringe.

Ingredients

Active ingredient:

- each syringe contains 250 micrograms of ganirelix.

Inactive ingredients:

- It also contains glacial acetic acid, mannitol and water for injection. The pH may have been adjusted with sodium hydroxide and/or acetic acid.

Sponsor Details

Ganirelix-AFT is supplied in New Zealand by:

AFT Pharmaceuticals Ltd.
Auckland

Phone: +64-9-488-0232

Email: customer.service@aftp pharm.com

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