

# ARX GANIRELIX injection

## 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 ARX GANIRELIX injection?

ARX GANIRELIX injection contains the active ingredient ganirelix acetate. ARX GANIRELIX injection is used with other medications to regulate hormone response in women undergoing Assisted Reproductive Technology such as in vitro fertilisation. This medicine works by preventing women from 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 ARX GANIRELIX injection?](#) in the full CMI.

### 2. What should I know before I am use ARX GANIRELIX injection?

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 am given ARX GANIRELIX injection?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ARX GANIRELIX 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 ARX GANIRELIX injection?

- Treatment with ARX GANIRELIX injection should be started under the supervision of a fertility specialist. It is given as a injection under the skin in the thigh or stomach. The injection site should be changed every day.
- If your doctor or nurse decides you can give the injections yourself, they will teach you the injection technique.
- The usual dose is the contents of one pre-filled syringe once a day on specific days of the menstrual cycle. Your doctor will tell you when to inject ARX GANIRELIX injection.

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

### 5. What should I know while using ARX GANIRELIX injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ARX GANIRELIX injection.</li><li>• Contact your doctor immediately if you have severe pelvic pain, nausea and vomiting, or weight gain.</li><li>• Keep all of your doctor's appointments to monitor your progress. Your doctor will check the development of eggs inside the ovaries by an ultrasound examination and measuring hormones in your blood.</li><li>• Tell the hospital doctor that you are using this medicine if you need to have an operation, or go to hospital.</li><li>• If you are about to start a new medicine, tell your doctor or pharmacist that you are using ARX GANIRELIX injection.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• If you are self injecting, do not stop using this medicine or change the dose without talking to your doctor.</li><li>• Do not give this medicine to anyone else, or use this medicine to treat any other complaints.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• No effects on ability to drive and use machines have been observed.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep ARX GANIRELIX injection in a safe place away from the sight and reach of children.</li><li>• Keep ARX GANIRELIX injection below 30°C in the outer carton. Do not put it in the freezer.</li></ul>

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

### 6. Are there any side effects?

Common side effects include redness, pain or swelling at injection site, headache, nausea, and tiredness.

Serious side effects include shortness of breath, wheezing, difficulty breathing, a tight feeling in your chest, swelling of the face, lips, tongue and/or throat that may cause breathing or swallowing difficulty, or other parts of the body, rash, itching, hives 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.

# ARX GANIRELIX injection

Active ingredient: ganirelix acetate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX GANIRELIX injection. **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 ARX GANIRELIX injection.**

Where to find information in this leaflet:

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

## 1. Why am I using ARX GANIRELIX injection?

ARX GANIRELIX injection contains the active ingredient ganirelix acetate.

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

ARX GANIRELIX injection 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.**

## 2. What should I know before I use ARX GANIRELIX injection?

### Warnings

**Do not use ARX GANIRELIX injection if:**

- you are allergic (hypersensitive) to ganirelix or to any other components of ARX GANIRELIX injection, including the ingredients listed at the end of this leaflet  
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 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 ARX GANIRELIX injection, talk to your doctor.

### Check with 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

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?](#)

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 ARX GANIRELIX injection and seek immediate medical assistance.

### Pregnancy and breastfeeding

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

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

### Congenital malformations

The incidence of congenital malformations (a physical defect present in a baby at birth) after assisted reproductive technology (ART) may be slightly higher than after spontaneous conceptions. This may be due other factors (e.g. age of the female, sperm characteristics, multiple gestations after ART). The incidence of congenital malformations after ART using ARX GANIRELIX injection is not different from using different ART treatments.

## 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.

ARX GANIRELIX injection must not be mixed with other medicinal products.

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

## 4. How do I use ARX GANIRELIX injection?

### How to use

Treatment with ARX GANIRELIX injection should be started under the supervision of a fertility specialist.

ARX GANIRELIX injection 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 ARX GANIRELIX injection once a day on specific days of the menstrual cycle. Your doctor will tell you when to inject ARX GANIRELIX injection.

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 ARX GANIRELIX injection

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 ARX GANIRELIX pack and remove the plastic container. Carefully open the plastic container and remove the ARX GANIRELIX 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 ARX GANIRELIX.

#### 4. Inserting the needle and injecting

ARX GANIRELIX 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 ARX 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.

### How long to use ARX GANIRELIX injection

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

### If you forget to use ARX GANIRELIX injection

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

If you think that you have used too much ARX GANIRELIX, 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 ARX GANIRELIX injection

### 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 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 ARX GANIRELIX injection.

Tell the hospital doctor that you are using ARX GANIRELIX injection 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 ARX GANIRELIX injection.

### Things you must not do

If you are self injecting:

- do not stop using ARX GANIRELIX injection 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.

### Driving or using machines

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

### Looking after your medicine

Keep ARX GANIRELIX injection 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. Follow the instructions in 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.

A locked cupboard at least one-and-a-half-metres above the ground is a good place to store medicines

**Keep it where young children cannot reach it.**

### When to discard your medicine

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

### 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.

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

## 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"> <li>• redness, pain or swelling at injection site. Usually these symptoms disappear within a few hours after injection.</li> <li>• headache</li> <li>• nausea</li> <li>• tiredness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>• shortness of breath,</li> <li>• wheezing</li> <li>• a tight feeling in your chest</li> <li>• breathing difficulties</li> </ul> <p><b>Swelling, of the</b></p> <ul style="list-style-type: none"> <li>• face</li> <li>• lips</li> <li>• tongue</li> <li>• throat (that may cause difficulty in breathing or swallowing),</li> <li>• other parts of the body</li> </ul> <p><b>Skin Reactions</b></p> <ul style="list-style-type: none"> <li>• rash,</li> <li>• itching</li> <li>• hives (urticaria)</li> <li>• flushed, red skin</li> </ul> <p><b>Gastrointestinal changes</b></p> <ul style="list-style-type: none"> <li>• indigestion</li> <li>• nausea</li> <li>• vomiting</li> <li>• diarrhoea</li> </ul> <p><b>Renal changes</b></p> <ul style="list-style-type: none"> <li>• reduced amounts of urine</li> </ul> <p><b>Reproductive /hormonal changes</b></p> <ul style="list-style-type: none"> <li>• painful breasts</li> <li>• weight gain</li> <li>• vaginal bleeding</li> <li>• miscarriage</li> <li>• ectopic pregnancy (embryo implanted outside the womb)</li> </ul>	<p><b>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.</b></p>

**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](http://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. This medicine is not addictive.

### **What ARX GANIRELIX injection contains**

<b>Active ingredient (main ingredient)</b>	ganirelix acetate
<b>Other ingredients (inactive ingredients)</b>	glacial acetic acid mannitol sodium hydroxide water for injections

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

### **What ARX GANIRELIX injection looks like**

ARX GANIRELIX injection is a clear colourless solution. (AUST R 409682).

Each syringe contains 250 micrograms of ganirelix (as acetate).

ARX GANIRELIX injection is available in packs of 1 or 5 pre-filled syringes.

### **Who distributes ARX GANIRELIX injection**

Arrotex Pharmaceuticals Pty Ltd  
15 – 17 Chapel Street  
Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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