Orgalutran®

Ganirelix (as acetate) 250 micrograms in 0.5 millilitres

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Orgalutran.

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 taking Orgalutran 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 Orgalutran is used for

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.

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

Orgalutran is not addictive.

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

Before you use Orgalutran

When you must not use it

Do not use Orgalutran if:

- you are allergic (hypersensitive) to ganirelix or to any other components of Orgalutran, including the ingredients listed at the end of this leaflet and/or dry natural rubber/latex
- 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.

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 Orgalutran and seek immediate medical assistance.

The needle shield of Orgalutran contains dry natural rubber/ latex which comes into contact with this product and may cause allergic reactions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

How to 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.

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

Immediately contact your doctor or IVF clinic, or for Australia, the Poisons Information Centre (telephone 131 126), or for New Zealand, National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice if you think you have given yourself too much Orgalutran.

While you are Using Orgalutran

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 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 must not do

If you are self injecting:

- **do not stop using Orgalutran 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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Orgalutran.

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 side effects.

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 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.

After Using Orgalutran

Storage

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.

Keep Orgalutran 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.

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.

Product Description

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 of dry natural rubber/ latex which comes into contact with this product..

Ingredients

- each syringe contains 250 microgram of ganirelix
- inactive ingredients are acetic acid, mannitol and water for injections

Orgalutran is available in packs of 1 or 5 pre-filled syringes.

Identification

Orgalutran can be identified by the Australian Register Number on the carton: AUST R 74931

Distributed by

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Date leaflet revised:
February 2021
[CCPPI-MK-8761-INJ-122018]