

INFORMATION FOR THE CONSUMER

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Orgalutran® is used for
2. What Orgalutran® does
3. What Orgalutran® contains
4. What Orgalutran® looks like and contents of the pack
5. When Orgalutran® should not be used
6. Warnings and Precautions
7. How to use Orgalutran®
8. Possible side effects
9. How to store Orgalutran®

1. WHAT ORGALUTRAN® IS USED FOR

Orgalutran® is used to prevent the premature LH surges in women undergoing Controlled ovarian hyperstimulation (COH). Orgalutran allows the release of an egg to be controlled so that it occurs at an optimal time for pregnancy to occur.

2. WHAT ORGALUTRAN® DOES:

The active ingredient in Orgalutran® is ganirelix acetate, which is a gonadotrophin-releasing hormone (GnRH) antagonist. GnRH is a hormone produced in humans to regulate the release of other hormones called gonadotrophins: luteinising hormone (LH) and follicle stimulating hormone (FSH). Orgalutran blocks the action of GnRH to stop the release of gonadotrophins, especially LH.

In women, FSH is needed for growth and development of follicles in the ovaries. Follicles are small round sacs that contain the egg cells. LH is needed to release the mature egg cells from the follicles and ovaries (i.e. ovulation).

3. WHAT ORGALUTRAN® CONTAINS:

The active substance is ganirelix acetate.

The non-active ingredients are acetic acid, mannitol, water for injection, and sodium hydroxide.

4. WHAT ORGALUTRAN® LOOKS LIKE AND CONTENTS OF THE PACK:

Orgalutran® is available in pre-filled syringes and in packs of 1. Each pre-filled syringe contains 0.25 mg ganirelix in 0.5 ml sterile, ready to use, clear and colorless aqueous solution. Orgalutran® is to be injected under the skin (subcutaneous injection). **The needle cover contains dry natural rubber/latex which comes into contact with this product.**

5. WHEN ORGALUTRAN® SHOULD NOT BE USED:

Do not use ORGALUTRAN® if:

- you are allergic (hypersensitive) to ganirelix acetate or any other components of Orgalutran®, including dry natural rubber/latex
- you are hypersensitive to any products containing gonadotrophin releasing hormone (GnRH) or GnRH analog such as leuprolide acetate, goserelin acetate
- you have a moderate or severe kidney or liver disease
- you are pregnant

If any of these conditions apply to you, please tell your doctor before starting to use this medicine.

6. WARNINGS AND PRECAUTIONS:

Orgalutran® should be prescribed and managed by a doctor experienced in infertility treatment.

Before you use Orgalutran, tell your doctor if any of these conditions apply to you:

- if you are pregnant or breast-feeding
- if you have an allergy or any active allergic condition. Your doctor will decide, depending on the severity, if additional monitoring is required during treatment. Cases of allergic reactions, both generalized 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 8 POSSIBLE SIDE EFFECTS.) If you have an allergic reaction, stop taking Orgalutran and seek immediate medical assistance.
- if you are sensitive to natural rubber latex since the packaging of Orgalutran (needle cover) contains dry natural rubber/latex which comes into contact with this product and may cause allergic reactions.
- If you are taking or have recently taken other medications including those not requiring a prescription
- if you weigh less than 50 kg or more the 90 kg

The incidence of ectopic pregnancies might be increased in women undergoing assisted reproduction. Your doctor will perform an ultrasound scan early during pregnancy to confirm that a pregnancy is intrauterine.

The incidence of congenital malformations after assisted reproduction techniques may be slightly higher than after spontaneous conceptions. This slightly higher incidence is thought to be related 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 assisted reproduction techniques. The incidence of congenital malformations after assisted reproduction techniques using Orgalutran is not different from that after using other GnRH analogues in the course of assisted reproduction techniques.

7. HOW TO USE ORGALUTRAN®

Always use Orgalutran® exactly as your doctor has told you. You should check with your doctor if you are not sure.

If you inject more Orgalutran than you should, contact your doctor.

In case of overdose, contact your doctor or pharmacist, emergency department of the nearest hospital, or a poison control centre immediately.

Orgalutran (0.25 mg) should be injected just under the skin once daily, as directed.

Orgalutran and product containing FSH should be used at approximately the same time. However, the preparations should not be mixed together and different injection sites are to be used.

Daily treatment with Orgalutran should be continued for the time interval determined by your doctor. Your doctor can determine this using techniques such as ultrasound.



Instructions for use

Injection site

Orgalutran is supplied in pre-filled syringes and should be injected slowly, just under the skin, preferably in the upper leg.

Inspect the solution before use. Do not use if the solution contains particles or is not clear. If you administer the injections yourself or have it done by your partner, follow the instructions below carefully. Do not mix Orgalutran with any other medicines.

Preparing the injection site

Wash your hands thoroughly with soap and water.



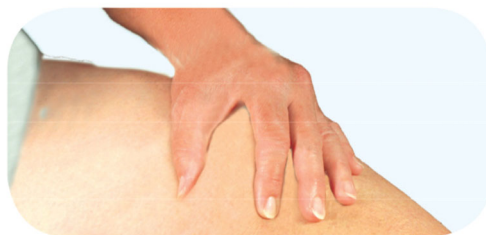
Swab the injection site with a cotton swab moistened with disinfectant (for example rubbing alcohol) to remove any surface bacteria on the skin. The most convenient site for subcutaneous injection is in the upper thigh. Clean about 5 cm (two inches) around the point where the needle will go in and let the disinfectant dry for at least one minute before proceeding.



Inserting the needle

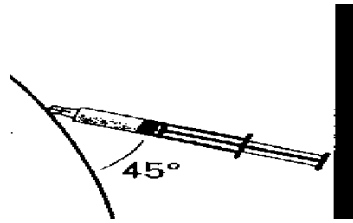
With syringe held upright, remove needle cover.

Pinch up a large area of skin between finger and thumb.



Insert the needle at the base of the pinched-up skin at an angle of 45°- 90° to the skin

surface. Change the injection site with each injection.



Checking the correct needle position

Gently draw back the plunger to check if the needle is positioned correctly. Any blood drawn into the syringe means the needle tip has penetrated a blood vessel. If this happens, do not inject Orgalutran®, but remove the syringe, cover the injection site with a swab containing disinfectant and apply pressure; bleeding should stop in a minute or two.



Do not use this syringe and dispose of it properly. Start again with a new syringe.

Injecting the solution

After the needle position has been checked as described above, depress the plunger slowly and steadily, so the solution is correctly injected and the skin tissues are not damaged.

Removing the syringe

Pull the syringe out quickly and apply pressure to the site with a swab containing disinfectant (see above diagram).

Use the pre-filled syringe only once and dispose of it properly.

If you inject more Orgalutran® than you should:

Contact your doctor.

If you forget to inject Orgalutran®:

If you realize that you forgot a dose, administer it as soon as possible.

Do not inject a double dose to make up for forgotten individual doses.

If you are more than 6 hours late (so the time between two injections is longer than 30 hours) administer the dose as soon as possible, **and** contact your doctor for further advice.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

8. POSSIBLE SIDE EFFECTS

Like all medicines, Orgalutran® can cause side effects or reactions.

Orgalutran may cause a skin reaction such as redness, with or without swelling at the injection site. These skin reactions normally disappear within 4 hours of injection.

Very rarely, allergic reactions including the following have been observed, as early as with the first dose:

- rash,
- facial swelling,
- difficulty breathing (dyspnea),
- swelling of the face, lip, tongue and/or throat that may cause difficulty in breathing or swallowing (angioedema and/or anaphylaxis),
- hives (urticaria)

Other side effects may be headache, nausea, dizziness, asthenia (lack or loss of strength and energy) and malaise (general unwell feeling).

Additional side effects which have been known to occur with controlled ovarian hyperstimulation treatment include abdominal pain, ovarian hyperstimulation syndrome (OHSS), ectopic pregnancy (fertilized egg attaches to fallopian tube instead of the womb) and miscarriage.

During or following hormonal stimulation of the ovaries, ovarian hyperstimulation syndrome may develop. Ovarian hyperstimulation syndrome (OHSS) is a rare condition which occurs when too many follicles (part of the ovary that forms into an egg) grow and cause abdominal distension, abdominal discomfort or pain, nausea, diarrhea and sometimes difficulty in breathing. If you experience these symptoms, contact your doctor immediately as OHSS is a very serious side effect which may require treatment in the hospital.

There is one case where a patient who had eczema reported that it got worse after the first Orgalutran dose.

The effects of Orgalutran® on the ability to drive and use machines have not been studied.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

9. HOW TO STORE ORGALUTRAN®

Keep out of the reach and sight of children

Do not freeze. Store at room temperature between 15°C and 30°C.

Store in the original package in order to protect from light.

Do not use after the expiry date stated on the carton and on the label.

Inspect the syringe before use. Use only syringes with clear, particle-free solutions and from undamaged containers.

Contains no preservatives, therefore, each syringe is to be used only once and then properly disposed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.