

RA 2450 OS P3 (ref 4.0)

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Orgalutran<sup>®</sup>, 0.25 mg/0.5mLSolution for injection  
ganirelix**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 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 and what it is used for
2. Before you use Orgalutran
3. How to use Orgalutran
4. Possible side effects
5. How to store Orgalutran
6. Further information

**1. WHAT ORGALUTRAN IS AND WHAT IT IS USED FOR**

Orgalutran contains ganirelix, which inhibits actions of the natural gonadotrophin releasing hormone (GnRH). GnRH regulates the release of gonadotrophins (luteinising hormone (LH) and FSH). Gonadotrophins play an important role in human fertility and reproduction. In women, FSH is needed for the 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). Orgalutran inhibits the action of GnRH, resulting in suppression of the release of especially LH.

**Therapeutic indication:**

In women undergoing assisted reproduction techniques (ART), including *in vitro* fertilisation (IVF) and other methods, occasionally ovulation may occur too early causing a significant reduction in the chance of getting pregnant. Orgalutran is used to prevent the premature LH surge that might cause such a premature release of egg cells. Orgalutran is used to prevent premature luteinisation during controlled ovarian stimulation for assisted reproduction techniques.

In clinical trials Orgalutran was used with recombinant follicle stimulating hormone (FSH).

**2. BEFORE YOU USE ORGALUTRAN****Do not use Orgalutran**

- if you are allergic (hypersensitive) to ganirelix or any of the other ingredients of Orgalutran.
- if you are hypersensitive to gonadotrophin-releasing hormone (GnRH) or a GnRH analogue
- if you have a moderate or severe kidney or liver disease
- if you are pregnant or breast-feeding

Do not use Orgalutran if you have any of the conditions listed above. If any of these conditions apply to you, please tell your doctor before starting to use this medicine.

**Take special care with Orgalutran**

- If you have an allergy
- If you have an active allergic condition, please tell your doctor. He will decide, depending on the severity, if additional monitoring is required during treatment.

During or following hormonal stimulation of the ovaries ovarian hyperstimulation syndrome may develop; this syndrome is related to the stimulation procedure with gonadotrophins; please refer to the Package Leaflet of the gonadotrophin-containing medicine prescribed for you.

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.

The efficacy and safety of Orgalutran has not been established in women weighing less than 50 kg or more than 90 kg. Ask your doctor for further information.

**Pregnancy**

Do not use Orgalutran

**Breast-feeding**

Do not use Orgalutran

**Driving and using machines**

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

**Using other medicines**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those medicines obtained without a prescription.

**3. 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.

Orgalutran is used as part of the treatment for assisted reproduction techniques (ART) including *in-vitro* fertilization (IVF).

Ovarian stimulation with follicle stimulating hormone (FSH) may start at day 2 or 3 of your period. Orgalutran (0.25 mg) should be injected just under the skin once daily, starting on day 6 of FSH administration. Based on your response to FSH, your doctor may decide to start on another day. Orgalutran and FSH should be administered approximately at the same time. However, the preparations should not be mixed and different injection sites are to be used.

Daily treatment with Orgalutran should be continued up to the day that sufficient follicles of adequate size are present. Final maturation of the egg cells in the follicles can be induced by administering human chorionic gonadotrophin (hCG). The time between two Orgalutran injections as well as the time between the last Orgalutran injection and hCG injection should not exceed 30 hrs, as otherwise a premature ovulation (i.e. release of egg cells) may occur. Therefore, when injecting Orgalutran in the morning treatment with Orgalutran should be continued throughout the gonadotrophin treatment period including the day of triggering ovulation. When injecting Orgalutran in the afternoon the last Orgalutran injection should be given in the afternoon prior to the day of triggering ovulation.

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.

**Instructions for use****Preparing the injection site**

Wash your hands thoroughly with soap and water. Swab the injection site with a disinfectant (for example alcohol) to remove any surface bacteria. 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**

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° to the skin surface. Vary 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**

Once the needle has been correctly placed, 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. Use the pre-filled syringe only once.

**If you inject more Orgalutran than you should**

Contact your doctor

**If you forgot to use Orgalutran**

Do not inject a double dose to make up for a dose.

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

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 the impression that the effect of Orgalutran is too strong or too weak, talk to your doctor immediately.

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Orgalutran can cause side effects, although not everybody gets them. In about 1 in 10 patients Orgalutran may cause a local skin reaction at the site of injection (predominantly redness, with or without swelling). The local reaction normally disappears within 4 hours of administration. Very rarely, in less than 1 in 10.000 patients, more widespread possibly allergic reactions have been observed including various symptoms such as rash, facial swelling and dyspnoea.

Undesirable effects which may occur are headache, nausea and malaise. These effects occur in less than 1 in 100 patients.

In addition, undesirable effects are reported which are known to occur with controlled ovarian hyperstimulation treatment (e.g. pelvic pain, abdominal distension, ovarian hyperstimulation syndrome (OHSS), ectopic pregnancy and miscarriage).

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

**5. HOW TO STORE ORGALUTRAN**

Keep Orgalutran out of reach and sight of children.

Do not use Orgalutran after the expiry date stated on the carton and on the label after 'EXP':.

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

Store between 2°C and 30°C. Do not freeze.

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

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.

In correspondence please quote the packing number.

**6. FURTHER INFORMATION****What Orgalutran contains**

- The active substance is ganirelix (0.25 mg in 0.5 ml solution).
- The other ingredients are acetic acid and mannitol in water for injections. The pH may have been adjusted with sodium hydroxide and acetic acid.

**What Orgalutran looks like and contents of the pack**

Orgalutran is a clear and colorless aqueous solution for injection. The solution is sterile, ready for use and intended for subcutaneous administration.

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

**This leaflet was last revised in June, 2007.**

In correspondence please quote the Lot: number.

**Organon (Ireland) Limited, Swords, Co. Dublin, Ireland.**

**THIS IS A MEDICAMENT**

*Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.*

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

*Council of Arab Health Ministers, Union of Arab Pharmacists.*

GENERAL DETAILS		ECN No.:	n/a	Site of Origin:	SP Swords
Item No.:	56704649	Ver. No.:	02.A	Pharmacode No.:	221
Replacing:	51246	Pharmacode:	1011110	Colours:	Black
Description:	Leaflet Cross Fold Orgalutran	Barcode No.:	n/a		
Country:	Arabic Countries	Barcode Type.:	n/a	Status:	
Language:	Arab / English	Operator:	EMK	Date:	
Size:	435mm x 248mm	Date:	21 October 2008	Signature:	