Package leaflet: Information for the patient

Orgalutran®

0.25 mg/0.5 mL solution for injection

ganirelix

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Orgalutran is and what it is used for

Orgalutran contains the active substance ganirelix and belongs to a group of medicines called "anti- gonadotrophin-releasing hormones" which act against the actions of the natural gonadotrophin releasing hormone (GnRH). GnRH regulates the release of gonadotrophins (luteinising hormone (LH) and follicle stimulating hormone (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.

Orgalutran is used for

In women undergoing assisted reproduction techniques, 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.

In clinical studies Orgalutran was used with recombinant follicle stimulating hormone (FSH) or corifollitropin alfa, a follicle stimulant with a long duration of action.

2. What you need to know before you use Orgalutran

Do not use Orgalutran
- if you are allergic to ganirelix or any of the other ingredients of this medicine (listed in section 6);
- 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.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Orgalutran

Allergic reactions

If you have an active allergic condition, please tell your doctor. Your doctor will decide, depending on the severity, if additional monitoring is required during treatment. Cases of allergic reactions have been reported, as early as with the first dose.

Allergic reactions, both generalised and local, including hives (urticaria), swelling of the face, lips tongue and/or throat that may cause difficulty in breathing and/or swallowing (angioedema and/or anaphylaxis) have been reported. (See also section 4.) If you have an allergic reaction, stop taking Orgalutran and seek immediate medical assistance.

Latex allergy

The needle cover contains dry natural rubber/latex which comes into contact with the needle and may cause allergic reactions.

Ovarian hyperstimulation syndrome (OHSS)

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.

Multiple births or birth defects

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 woman, 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.

Pregnancy complications

There is a slightly increased risk of pregnancy outside of the uterus (an ectopic pregnancy) in women with damaged fallopian tubes.

For Practitioner Only

Women weighing less than 50 kg or more than 90 kg

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.

Children and adolescents
There is no relevant use of Orgalutran in children or adolescents.

Other medicines and Orgalutran
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility
Orgalutran should be used during controlled ovarian stimulation for assisted reproduction techniques (ART). Do not use Orgalutran during pregnancy and breast-feeding.

Ask your doctor or pharmacist for advice before taking this medicine.
Driving and using machines
The effects of Orgalutran on ability to drive and use machines have not been studied.

Orgalutran contains sodium
Orgalutran contains less than 1 mmol sodium (23 mg) per injection, that is to say essentially 'sodium-free'.

3. How to use Orgalutran

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Orgalutran is used as part of the treatment for assisted reproduction techniques (ART) including
in vitro fertilisation (IVF).
Ovarian stimulation with follicle stimulating hormone (FSH) or corifollitropin 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 5 or day 6 of stimulation. Based on your ovarian response, 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 hours, 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.

Instructions for use
Parenteral products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

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. You may notice air bubble(s) in the pre-filled syringe. This is expected, and removal of the air bubble(s) is not needed. 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 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 use more Orgalutran than you should
Contact your doctor.

If you forget to use Orgalutran
If you realise that you forgot a dose, administer it as soon as possible. Do not inject a double dose to make up for a forgotten dose.
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 stop using Orgalutran
Do not stop using Orgalutran unless advised to by your doctor, as this may affect the outcome of your treatment.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The chance of having a side effect is described by the following categories:

Very common: may affect more than 1 in 10 women
– Local skin reactions at the site of injection (predominantly redness, with or without swelling). The local reaction normally disappears within 4 hours of administration.

Uncommon: may affect up to 1 in 100 women
– Headache
– Nausea
– Malaise

Very rare: may affect up to 1 in 10,000 women
– Allergic reactions have been observed, as early as with the first dose.
  - Rash
  - Facial swelling
  - Difficulty breathing (dyspnoea)
  - Swelling of face, lips, tongue, and/or throat that may cause difficulty in breathing and/or swallowing (angioedema and/or anaphylaxis)
  - Hives (urticaria)
– Worsening of a pre-existing rash (eczema) has been reported in one subject after the first Orgalutran dose.

In addition, side effects are reported which are known to occur with controlled ovarian hyperstimulation treatment (e.g. abdominal pain, ovarian hyperstimulation syndrome (OHSS), ectopic pregnancy (when the embryo develops outside the womb) and miscarriage (see the patient information leaflet of the FSH-containing preparation you are treated with)).
Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Orgalutran

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30 ° C .Do not freeze.
Store in the original package, in order to protect from light.
Inspect the syringe before use. Use only syringes with clear, particle-free solutions and from undamaged containers.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Orgalutran contains
- The active substance is ganirelix (0.25 mg in 0.5 mL solution).
- The other ingredients are acetic acid, mannitol, water for injections. The pH (a measurement of the acidity) may have been adjusted with sodium hydroxide and acetic acid.

What Orgalutran looks like and contents of the pack
Orgalutran is a clear and colourless aqueous solution for injection. The solution is ready for use and intended for subcutaneous administration. **The needle cover contains dry natural rubber/latex which comes into contact with the needle.**

Orgalutran is available in packs of 1 or 5 pre-filled syringes. Not all pack sizes may be marketed.
Marketing Authorisation Holder and Manufacturer and Batch Releaser

Marketing Authorisation Holder
N.V. Organon, Kloosterstraat 6, 5349 AB OSS, The Netherlands.

Manufactured by
Vetter Pharma –Fertigung, GmbH & Co. KG, Schutzenstrasse 87 and 99-101, 88212 Ravensburg Germany

Released by
N.V. Organon, Kloosterstraat 6, 5349 AB OSS, The Netherlands.

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ORGANON

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