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MSD ARTWORK

Item No.:
Revision Date & No.:
Plant Code:
Schawk Job No.:
ACFID:

Black Yellow
Technical Info Profile

SCHAWKI
Proprietary

Mock-Up Design Workflows:
Placeholders (*) where component number will be placed upon approval.

ORGALUTRAN®
Ganirelix Acetate Injection



PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ORGALUTRAN®
Ganirelix Acetate Injection

Read this carefully before you start taking **ORGALUTRAN®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ORGALUTRAN®**.

What is ORGALUTRAN® used for?

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

How does ORGALUTRAN® work?

The active ingredient in ORGALUTRAN® is ganirelix acetate, which blocks a hormone in your body called gonadotrophin-releasing hormone (GnRH) antagonist. GnRH is a hormone that controls other hormones called gonadotrophins. These include luteinising hormone (LH) and follicle stimulating hormone (FSH). 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). ORGALUTRAN® blocks the action of GnRH to stop the release of gonadotrophins, especially LH.

What are the ingredients in ORGALUTRAN®?

Medicinal ingredients: ganirelix acetate
Non-medicinal ingredients: glacial acetic acid, mannitol, water for injection (adjusted to pH 5.0 with acetic acid and / or sodium hydroxide).

ORGALUTRAN® comes in the following dosage forms:

As a sterile solution containing 250 mcg ganirelix / 0.5 mL.

Do not use ORGALUTRAN® if you:

- are allergic to ganirelix acetate
- are allergic to any other ingredients in ORGALUTRAN®
- are allergic to any part of the ORGALUTRAN® container, including to dry natural rubber or latex. The needle shield on ORGALUTRAN® contains dry natural rubber / latex. It comes in contact with ORGALUTRAN® and can cause allergic reactions.
- are hypersensitive to any products containing GnRH or GnRH analog such as leuprolide acetate and goserelin acetate
- have moderate or severe kidney disease
- have moderate or severe liver disease
- are pregnant or think you might be pregnant
- are breast feeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ORGALUTRAN®. Talk about any health conditions or problems you may have, including if you:

- weigh less than 50 kg (110 lbs) or more than 90 kg (198 lbs)

Other warnings you should know about:

Ectopic pregnancy:
An ectopic pregnancy is where the fetus develops outside the uterus. You are more likely to have an ectopic pregnancy with assisted reproduction. Your doctor will perform an ultrasound scan early during pregnancy to confirm that your pregnancy is not ectopic.

Birth defects:
The risk of birth defects may be slightly higher following infertility treatment.

Allergy:
Tell your doctor if you have an allergy. Your doctor will decide if you need to be more closely monitored during treatment. If you have a severe allergic condition, such as angioedema or anaphylaxis, ORGALUTRAN® might not be right for you. Tell your doctor if you have a severe allergic condition. Allergic reactions have been reported with ORGALUTRAN® treatment. Stop taking ORGALUTRAN® and get immediate medical help if you have any of the following symptoms:

- difficulty breathing or swallowing
- hives
- swelling of the face, lips, tongue or throat
- rash

Ovarian hyperstimulation syndrome (OHSS):
During or following hormonal stimulation of the ovaries, ovarian hyperstimulation syndrome may develop. This is when a very large

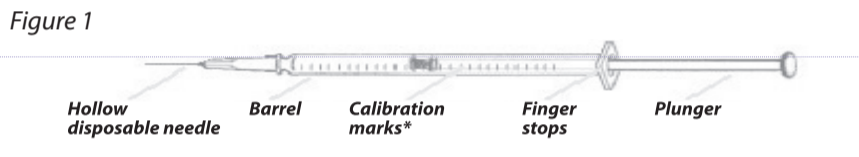
number of follicles begin to grow. Your doctor will monitor you for this condition, but you should talk to your doctor if you are having:

- abdominal swelling
- abdominal discomfort or pain
- nausea
- diarrhea
- difficulty in breathing.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take ORGALUTRAN®:

- ORGALUTRAN® will be prescribed by a doctor with experience in infertility treatment.
- Always use ORGALUTRAN® exactly as your doctor has told you.
- Check with your doctor if you are not sure how to use ORGALUTRAN®.
- Efficacy and safety of ORGALUTRAN® have not been studied in women for more than 3 cycles in a row.
- You should inject ORGALUTRAN® under your skin, once a day, as directed by your doctor.
- It should be injected at about the same time as products containing FSH. But, you should not mix the products together and they should be injected at different sites on your body.
- Your doctor will tell you for how long you should inject ORGALUTRAN®.
- Discuss with your doctor about risk of possible reactions to ORGALUTRAN®.
- They will monitor your treatment by using ultrasound.
- Follow the "instructions for use", below, when injecting ORGALUTRAN®.



Instructions for use

Injection site:
ORGALUTRAN® is supplied in a pre-filled syringe. It should be injected slowly, just under the skin, preferably in the upper leg. Inspect the ORGALUTRAN® before use. Do not use if the liquid inside the syringe contains particles or is not clear. You may notice air bubbles in the pre-filled syringe. This is normal and you do not need to remove the air bubbles. Follow the instructions below carefully. You can inject ORGALUTRAN® yourself or have it injected by someone else. Do not mix ORGALUTRAN® with any other medicines.

Preparing the injection site:
Wash your hands well with soap and water.



Swab the injection site with a cotton swab moistened with disinfectant (for example, rubbing alcohol). This removes bacteria from your skin. The most convenient site for subcutaneous injection is in the upper thigh. Clean about a 5 cm (two inches) area where the needle will go in. Let the disinfectant dry for at least one minute before proceeding.



Inserting the needle:
Hold the syringe with needle facing down. Remove needle cover. Pinch up a large area of skin between the 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 daily 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®. Remove the syringe, cover the injection site with a swab containing disinfectant and apply pressure. The 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 ORGALUTRAN®:
Depress the plunger slowly and steadily. This is done so that ORGALUTRAN® is injected correctly and the skin tissues are not damaged.

Removing the syringe:
Pull the syringe out quickly. Apply pressure to the site with a swab containing disinfectant (see diagram below). Use each syringe only once. Dispose of used syringe properly.



Usual dose:
250 mcg ORGALUTRAN® once a day (the contents of one 0.5 mL pre-filled syringe).

Overdose:
If you inject more ORGALUTRAN® than you should, contact your doctor.

If you think you have taken too much ORGALUTRAN® contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you realize that you forgot a dose, administer it as soon as possible. Do not inject a double dose to make up for a missed 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 have any further questions on the use of this product, ask your doctor or pharmacist.

What are possible side effects from using ORGALUTRAN®?
These are not all the possible side effects you may have when taking ORGALUTRAN®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Redness, swelling of skin at the injection site.
- Headache.
- Nausea.
- Dizziness.
- Tiredness and malaise (general feeling of being unwell).
- Abdominal pain.
- Hot flushes.
- Pain.
- Vaginal bleeding.

| Serious side effects and what to do about them | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| VERY RARE Allergic reaction: difficulty breathing or swallowing, hives, swelling of the face, lips, tongue or throat, rash. | | | ✓ |
| UNKNOWN Ectopic pregnancy (fetus develops outside the uterus): vaginal bleeding or spotting, cramping or pain in abdomen, lightheadedness or fainting, shoulder pain | | | ✓ |
| Miscarriage (loss of pregnancy): cramping or pain in abdomen, vaginal bleeding, fluid or tissue passing from your vagina. | | | ✓ |
| Ovarian Hyperstimulation Syndrome (OHSS): abdominal swelling, abdominal discomfort or pain, nausea, diarrhea, difficulty in breathing. | | | ✓ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Keep out of reach and sight of children.
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. Each syringe is for single use only.

If you want more information about ORGALUTRAN®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.organon.ca, or by calling 1-844-820-5468.

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MSD PROFILE

Profile: BS 12_360
Profile Revision: 02
Profile Revision Date: 030812
Dimensions (mm): 485 x 435.5

Over Sticker Varnish Free Text Free

Pharma Code Braille Grid Tamper Evident

Profile Perforation Fold