Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Ganirelix Taro 0.25 mg/0.5 ml
Solution for Injection, for Subcutaneous Use

Active ingredient
Each pre-filled syringe contains:
0.25 mg ganirelix in 0.5 ml aqueous solution.
Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?
Ganirelix Taro is intended for prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian stimulation in the setting of fertility treatments.

Therapeutic group: anti-gonadotrophin-releasing hormones.

Ganirelix Taro acts against the action of the natural gonadotrophin releasing hormone (GnRH). GnRH regulates the release of sex hormones (gonadotrophins), LH (luteinising hormone) and FSH (follicle stimulating hormone).
Gonadotrophins play a major role in female and male 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 (ovulation). Ganirelix Taro inhibits the action of GnRH, thus suppressing mainly the release of LH.

Ganirelix Taro use
In women undergoing fertility treatments, including in vitro fertilisation (IVF) and other methods, occasionally ovulation may occur too early, causing a significant reduction in the chance of achieving pregnancy. Ganirelix Taro use is intended to prevent the premature LH surge that might cause premature release of egg cells.

In clinical studies, Ganirelix Taro was used with recombinant follicle stimulating hormone (FSH) or corifollitropin alfa, a long-acting follicle stimulant.

2. Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to ganirelix or to any of the other ingredients of Ganirelix Taro (for a list of all the ingredients, see section 6);
- You suffer from hypersensitivity to gonadotrophin releasing hormone (GnRH) or to a GnRH analogue;
- You have a moderate or severe kidney or liver disease;
- You are pregnant or breastfeeding.

Special warnings about using Ganirelix Taro
Before using Ganirelix Taro, tell your doctor if:

- Allergic reactions: If you have an active allergic reaction, please tell your doctor. Your doctor will decide, depending on the condition 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 local and generalised, including rash (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 Ganirelix Taro 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 procedure of stimulation with gonadotrophins. Please refer to the patient leaflet of the gonadotrophin-containing medicine prescribed for you.
- Multiple births or birth defects: The incidence of congenital malformations after fertility treatments may be slightly higher than after spontaneous conception. This slightly higher incidence is probably related to characteristics of the patients undergoing fertility treatments (e.g. age of the woman, sperm characteristics), and to the higher incidence of multiple gestations after fertility treatments. The incidence of congenital malformations after fertility treatments with Ganirelix Taro is not different from the incidence of congenital malformations after fertility treatments including other GnRH analogues.
- Pregnancy complications: There is a slightly increased risk of pregnancy outside of the uterus (an ectopic pregnancy) in women with damaged fallopian tubes.
- Women weighing less than 50 kg or more than 90 kg: The efficacy and safety of Ganirelix Taro has not been established in women weighing less than 50 kg or more than 90 kg. Consult your doctor for further information.

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

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility
Ganirelix Taro should be used during controlled ovarian stimulation in the setting of fertility treatments. Do not use Ganirelix Taro during pregnancy and breastfeeding.
If you are pregnant or breastfeeding, consult the doctor or pharmacist before using any medicine.

Driving and using machines
The effects of Ganirelix Taro on the ability to drive or operate machines have not been studied.

Important information about some of this medicine's ingredients
This medicine contains less than 1 mmol (23 mg) sodium per injection, that is to say essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Ganirelix Taro is used as part of the treatment in women undergoing fertility treatments, including in vitro fertilisation (IVF).

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:
Ovarian stimulation with follicle stimulating hormone (FSH) or corifollitropin may start at day 2 or 3 of the menstrual period. Ganirelix Taro (0.25 mg) should be injected subcutaneously once daily, starting on day 5 or day 6 of stimulation initiation. Based on your ovarian response, your doctor may decide to start administration on another day.
Ganirelix Taro and FSH should be injected approximately at the same time. However, the preparations should not be mixed and different injection sites should be used.

Daily treatment with Ganirelix Taro 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 hCG (human chorionic gonadotrophin). The interval between two Ganirelix Taro injections, as well as the interval between the last Ganirelix Taro injection and hCG injection should not exceed 30 hours, as otherwise premature ovulation (release of egg cells) may occur. Therefore, when injecting Ganirelix Taro in the morning, treatment with Ganirelix Taro should be continued throughout the gonadotrophin treatment period, including the day of ovulation induction. When injecting Ganirelix Taro in the afternoon, the last Ganirelix Taro injection should be given in the afternoon prior to the day of ovulation induction.
Do not exceed the recommended dose.

Instructions for use
Injection site
Ganirelix Taro is supplied in a pre-filled syringe and should be injected slowly, under the skin, preferably in the thigh area.
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 for injection provided below. Do not mix Ganirelix Taro with any other medicines.

Preparing the injection site
Wash your hands thoroughly with soap and water. Disinfect the injection site with a disinfectant (for example alcohol) to remove any surface bacteria. Clean an area of about 5 cm around the site where the needle is to be inserted and let the disinfectant dry for at least one minute before proceeding.

Inserting the needle
Remove the needle cover. Pinch a large area of skin between the finger and thumb. Insert the needle at the base of the pinched 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 syringe plunger to check that the needle is positioned correctly. Any blood drawn into the syringe indicates that the needle has penetrated a blood vessel. In such case, do not inject Ganirelix Taro, but remove the syringe, cover the injection site with a disinfectant containing swab and apply pressure to the site; bleeding should stop within 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, to ensure that 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 disinfectant containing swab.

Use the pre-filled syringe only once.

If you have accidentally taken a higher dose than you should
Contact your doctor.

If you forgot to use Ganirelix Taro
If you realise that you forgot a dose, inject 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), inject the dose as soon as possible and contact your doctor for further instructions.

If you stop using Ganirelix Taro
Do not stop using Ganirelix Taro unless advised to do so by your doctor, as this may affect the treatment outcomes.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects
As with any medicine, using Ganirelix Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The chance of having a side effect is described by the following categories:
Very common side effects: may affect more than 1 in 10 women
- Local skin reactions at the injection site (predominantly redness, with or without swelling). The local reaction normally disappears within 4 hours of administration.

Uncommon side effects: may affect up to 1 in 100 women
- Headache
- Nausea
- Malaise.

Very rare side effects: 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)
- Rash (urticaria)
- Worsening of a pre-existing rash (eczema) has been reported in one subject after the first Ganirelix Taro dose.

In addition, side effects 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 leaflet of the FSH-containing preparation you are treated with)) have been reported.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**: Store at room temperature below 25ºC. Do not freeze. Store in the original package to protect from light.
- Inspect the syringe before use. Use only intact syringes containing a clear, particle-free solution and placed in intact containers.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Mannitol, glacial acetic acid, sodium hydroxide, water for injections.
What the medicine looks like and contents of the pack:
A clear and colourless solution for injection. The solution is ready for use and is intended for subcutaneous administration. **The needle cover contains dry natural rubber/latex, which comes into contact with the needle.**

Ganirelix Taro is available in packs of 1 pre-filled syringe.

Manufacturer's name and address:
Sun Pharmaceutical Industries Ltd., Halol Baroda Highway, Halol – Baroda Highway, Halol, Gujarat, 389350, INDIA

Registration holder's name and address:
Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Revised in February 2024 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry:
174-31-36968-99