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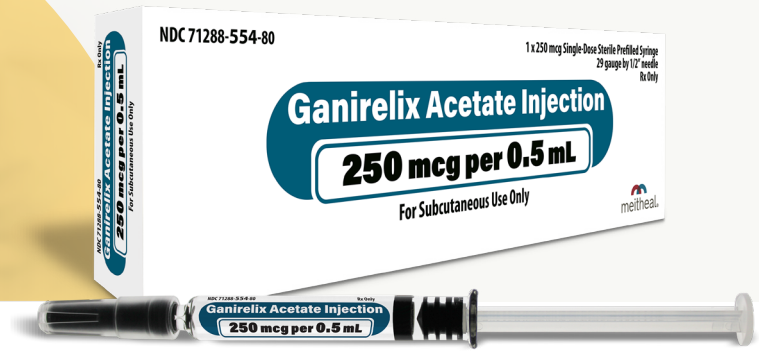


Directions for Using Ganirelix Acetate Injection

Ganirelix acetate injection is supplied in a single dose, sterile, prefilled syringe and is intended for SUBCUTANEOUS administration only.

Wash hands thoroughly with soap and water.

The most convenient sites for SUBCUTANEOUS injection are in the abdomen around the navel or upper thigh.

1 READY

Select and prepare your injection site

The injection site should be swabbed with a disinfectant to remove any surface bacteria. Clean about two inches around the point where the needle will be inserted and let the disinfectant dry for at least one minute before proceeding.

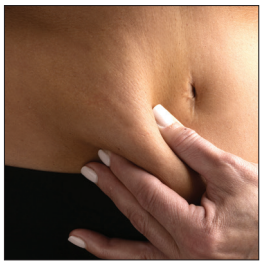
2 SET

Uncap your syringe

With syringe held upward, remove needle cover.

3 INJECT

Inject your Ganirelix Acetate Injection



- Pinch up a large area of skin between the finger and thumb. Vary the injection site a little with each injection.
- The needle should be inserted at the base of the pinched-up skin at an angle of 45–90° to the skin surface.
- When the needle is correctly positioned, it will be difficult to draw back on the plunger. If any blood is drawn into the syringe, the needle tip has penetrated a vein or artery. If this happens, withdraw the needle slightly and reposition the needle without removing it from the skin. Alternatively, remove the needle and use a new, sterile, prefilled syringe. Cover the injection site with a swab containing disinfectant and apply pressure; the site should stop bleeding within one or two minutes.
- Once the needle is correctly placed, depress the plunger slowly and steadily, so the solution is correctly injected and the skin is not damaged.
- Pull the syringe out quickly and apply pressure to the site with a swab containing disinfectant.
- Use the sterile, prefilled syringe only once. Discard the unused portion and dispose of it properly.

Please read the accompanying Prescribing Information for Ganirelix Acetate Injection, and discuss it with your doctor.

Storage. Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.]

Protect from light. Discard unused portion.

Sterile, Nonpyrogenic, Preservative-free.

The container closure is not made with natural rubber latex.

INDICATIONS AND USAGE

Ganirelix Acetate Injection is indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

CONTRAINDICATIONS

Ganirelix acetate is contraindicated under the following conditions:

- Known hypersensitivity to ganirelix acetate or to any of its components.
- Known hypersensitivity to GnRH or any other GnRH analog.
- Known or suspected pregnancy (see PRECAUTIONS).

WARNINGS

Ganirelix acetate injection should be prescribed by physicians who are experienced in infertility treatment. Before starting treatment with ganirelix acetate, pregnancy must be excluded. Safe use of ganirelix acetate during pregnancy has not been established (see **CONTRAINDICATIONS** and **PRECAUTIONS**).

PRECAUTIONS

General

Special care should be taken in women with signs and symptoms of active allergic conditions. Cases of hypersensitivity reactions, including anaphylactoid reactions, have been reported, as early as with the first dose, during post-marketing surveillance (see **ADVERSE REACTIONS**). In the absence of clinical experience, ganirelix acetate treatment is not advised in women with severe allergic conditions.

Information for Patients

Prior to therapy with ganirelix acetate, patients should be informed of the duration of treatment and monitoring procedures that will be required. The risk of possible adverse reactions should be discussed (see **ADVERSE REACTIONS**).

Ganirelix acetate should not be prescribed if the patient is pregnant.

ADVERSE REACTIONS

The safety of ganirelix acetate was evaluated in two randomized, parallel-group, multicenter controlled clinical studies. Treatment duration for ganirelix acetate ranged from 1 to 14 days. Table IV represents adverse events (AEs) from first day of ganirelix acetate administration until confirmation of pregnancy by ultrasound at an incidence of ≥ 1% in ganirelix acetate-treated subjects without regard to causality.

TABLE IV: Incidence of common adverse events (Incidence ≥ 1% in ganirelix acetate-treated subjects). Completed controlled clinical studies (All-subjects-treated group).

Adverse Events Occurring in > 1%	Ganirelix Acetate N=794 % (n)
Abdominal Pain (gynecological)	4.8 (38)
Death Fetal	3.7 (29)
Headache	3.0 (24)
Ovarian Hyperstimulation Syndrome	2.4 (19)
Vaginal Bleeding	1.8 (14)
Injection Site Reaction	1.1 (9)
Nausea	1.1 (9)
Abdominal Pain (gastrointestinal)	1.0 (8)

During post-marketing surveillance, rare cases of hypersensitivity reactions, including anaphylactoid reactions, have been reported, as early as with the first dose (see **PRECAUTIONS**).

Please read the accompanying Prescribing Information for Ganirelix Acetate Injection, and discuss it with your doctor.

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AD23-048

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