Directions for Using Cetrorelix Acetate for Injection

Cetrorelix Acetate for injection is supplied in a kit that contains one glass single-dose vial (0.25 mg Cetrorelix), one pre-filled glass syringe (1 mL of Sterile Water for Injection, USP), one 20 gauge needle, and one 27 gauge needle. Cetrorelix acetate 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 Mixing the powder and water to make your medicine

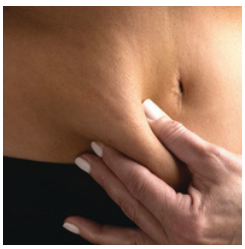
- Flip off the plastic cover of the vial. Wipe the aluminum ring and the rubber stopper with an alcohol swab.
- Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Twist the top off of the needle with the yellow mark. Gently twist the cover from the pre-filled syringe to remove, and then twist the yellow needle onto it. Remove the yellow needle cover.
- Push the needle through the center of the rubber stopper of the vial. Inject the water into the vial by slowly pushing down on the plunger of the syringe. Leave the syringe in the vial. While carefully holding the syringe and vial, swirl gently to mix the powder and water together. When it is mixed, it will look clear and have no particles in it. Do not shake or you will create bubbles in your medicine. Draw the total contents of the vial into the syringe. If liquid is left in the vial, invert the vial, pull back the needle until the opening of the needle is just inside the stopper. If you look from the side through the gap in the stopper, you can control the movement of the needle and the liquid.
  It is important to withdraw the entire contents of the vial. The backstop should NOT be removed—it is in place to ensure the plunger in the syringe can't be removed completely and the sterility of the medication isn't compromised.
- Put the cap back on the yellow needle. Gently unscrew the yellow needle from the syringe and lay down the syringe.

See FAQs for safe disposal of used needles, vial, and syringe.

2 Preparing injection site and syringe

- Take the injection needle with the gray mark and remove its wrapping. Twist the needle on the syringe and remove the cover of the needle.
- Invert the syringe and slowly push the plunger until all air bubbles have been pushed out. **Do not touch the needle or allow the needle to touch any surface.**
- Choose an injection site in the lower abdominal area, preferably around, but at least one inch away from the belly button. Choose a different injection site each day to minimize local irritation. Take a second alcohol swab and clean the skin at the injection site allowing the alcohol to dry.

3 Inject your Cetrorelix Acetate Injection



- With one hand, gently pinch up the previously cleaned skin around the chosen injection site. With the other, hold the syringe like you would hold a pencil. Insert needle at the base of the pinched-up skin at an angle of 45-90° to the skin surface.
- Slowly push down on the plunger until all of your medication is injected.
- Remove the needle from your skin at the same angle and put the cap back on the gray needle so it is safe to be thrown away. Use the syringe and needles only once. Properly dispose of the syringe and needles immediately after use.

Storage. Store Cetrorelix Acetate 0.25 mg refrigerated, 2-8°C (36-46°F). Store the packaged tray in the outer carton in order to protect from light.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Cetrorelix Acetate for injection is contraindicated under the following conditions:

- Hypersensitivity to Cetrorelix Acetate, extrinsic peptide hormones or mannitol.
- Known hypersensitivity to GnRH or any other GnRH analogs.
- Known or suspected pregnancy, and lactation (see PRECAUTIONS).
- Severe renal impairment.

WARNINGS

Cetrorelix Acetate for injection should be prescribed by physicians who are experienced in fertility treatment. Before starting treatment with Cetrorelix Acetate, pregnancy must be excluded (see CONTRAINDICATIONS and PRECAUTIONS.

PRECAUTIONS

General

Cases of hypersensitivity reactions, including anaphylactoid reactions with the first dose, have been reported during post-marketing surveillance (see ADVERSE REACTIONS). A severe anaphylactic reaction associated with cough, rash, and hypotension, was observed in one patient after seven months of treatment with Cetrorelix Acetate (10 mg/day) in a study for an indication unrelated to infertility. Special care should be taken in women with signs and symptoms of active allergic conditions or known history of allergic predisposition. Treatment with Cetorelix Acetate is not advised in women with severe allergic conditions.

Information for Patients

Prior to therapy with Cetrorelix Acetate for injection, 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). Cetrorelix Acetate should not be prescribed if a patient is pregnant. If Cetrorelix Acetate is prescribed to patients for self-administration, information for proper use is given in the Patient Leaflet (see below).

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ADVERSE REACTIONS

The safety of Cetrorelix Acetate for injection in 949 patients undergoing controlled ovarian stimulation in clinical studies was evaluated. Women were between 19 and 40 years of age (mean: 32). 94.0% of them were Caucasian. Cetrorelix Acetate was given in doses ranging from 0.1 mg to 5 mg as either a single or multiple dose.

Table 3 shows systemic adverse events, reported in clinical studies without regard to causality, from the beginning of Cetrorelix Acetate treatment until confirmation of pregnancy by ultrasound at an incidence ≥ 1% in Cetrorelix Acetate treated subjects undergoing COS.

Adverse Events in ≥1% (WHO preferred term)	Cetrorelix Acetate N=949% (n)
Ovarian Hyperstimulation Syndrome*	3.5 (33)
Nausea	1.3 (12)
Headache	1.1 (10)

*Intensity moderate or severe, or WHO Grade II or III, respectively

Local site reactions (e.g. redness, erythema, bruising, itching, swelling, and pruritus) were reported. Usually, they were of a transient nature, mild intensity and short duration. During postmarketing surveillance, cases of mild to moderate Ovarian Hyperstimulation syndrome and infrequent cases of hypersensitivity reactions including anaphylactoid reactions have been reported.

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

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