

INFORMATION FOR THE CONSUMER

This insert provides a summary of the information about CETROTIDE (cetorelix for injection). If you have any questions or concerns, or want more information about CETROTIDE, (cetorelix for injection) contact your doctor or pharmacist.

What is CETROTIDE (cetorelix for injection) used for?

CETROTIDE (cetorelix for injection) is used as part of the hormone treatment for ovarian stimulation. CETROTIDE (cetorelix for injection) blocks the effect of a natural hormone, called gonadotropin-releasing hormone (GnRH). GnRH controls the secretion of another hormone, called luteinizing hormone (LH). LH is the hormone that starts ovulation (release of an egg) during the menstrual cycle. CETROTIDE (cetorelix for injection) allows the release of an egg to be controlled so that it occurs at an optimal time for pregnancy to occur.

Who should not use CETROTIDE (cetorelix for injection)?

Before you use CETROTIDE (cetorelix for injection) let your doctor know of any of the following:

1. If you are taking or have recently taken other medications including those not requiring a prescription.
2. If you are allergic to cetorelix acetate or the non-active ingredient, mannitol.
3. If you are pregnant, or think that you might be pregnant, or if you are breast feeding.
4. If you are allergic to GnRH or any other GnRH analogs (e.g., leuprolide acetate, goserelin acetate).
5. If you have moderate or severe liver or kidney disease.

What Dosage Forms are Available?

CETROTIDE (cetorelix for injection) **0.25 mg** is available in a carton of one packaged tray containing: one glass vial of medication (white powder), one pre-filled syringe with Sterile Water for Injection, Ph.Eur. (liquid), one mixing needle (yellow), one injection needle (grey), and two alcohol swabs.

CETROTIDE (cetorelix for injection) **3 mg** is available in a carton of one packaged tray containing: one glass vial of medication (white powder), one pre-filled syringe with Sterile Water for Injection, Ph.Eur. (liquid), one mixing needle (yellow), one injection needle (grey), and two alcohol swabs.

Both strengths contain mannitol as the non-active ingredient.

How to use CETROTIDE (cetorelix for injection)?

Ovarian stimulation therapy is started on cycle Day 2 or 3. CETROTIDE (cetorelix for injection) is injected under the skin either once daily (0.25 mg dose) or once (3 mg dose), as directed by your physician. Your doctor will recommend the appropriate dose regimen for you.

How should you use CETROTIDE (cetrotide for injection)?

CETROTIDE (cetrotide for injection) should be injected under the skin, as a single dose of 3 mg once or as a multiple dose of 0.25 mg daily as directed by your doctor.

You may self-inject CETROTIDE (cetrotide for injection) after special instruction from your doctor.

CETROTIDE (cetrotide for injection) is for injection under the skin of the lower abdominal wall. If you are on a multiple dose (0.25 mg) regimen, choose a different injection site each day to minimize local irritation.

If you forget a dose

If you miss a dose of CETROTIDE (cetrotide for injection) do not double dose. Discuss with your doctor when you should receive your next dose. Check with your doctor if you have any questions about this.

How to prepare and administer CETROTIDE (cetrotide for injection):

Preparation of the Medication

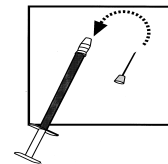
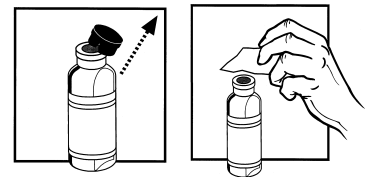
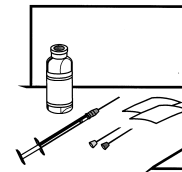
1. Clean your work surface with soap and water.

2. Wash your hands well with soap and water.

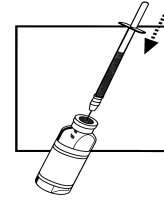
3. On a clean surface, lay out everything you need [one vial of medication, one pre-filled syringe, one needle for mixing (yellow mark), one needle for injection (grey mark) and two alcohol wipes].

4. Flip off the plastic cover of the vial of medication. Wipe the aluminum ring and rubber stopper with an alcohol wipe. Discard the alcohol wipe.

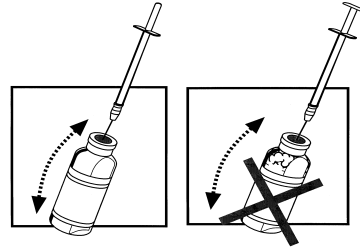
5. Take the needle for mixing (yellow mark) and remove the wrapping. Take the pre-filled syringe and remove the cover. Twist the needle onto the syringe so that it is tight. Carefully remove the cover of the needle by pulling it straight off.



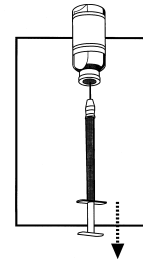
6. Push the needle through the center of the rubber stopper of the vial of medication. Inject the water from the pre-filled syringe into the vial by slowly pushing down the plunger of the syringe. Dissolve CETROTIDE (cetorelix for injection) powder only with the water contained in the pre-filled syringe.



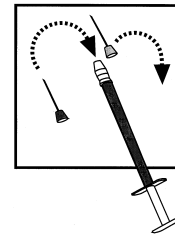
7. Without removing the needle from the vial, gently shake or rotate the vial until the solution is clear and without particles. Avoid forming bubbles. DO NOT USE IF SOLUTION APPEARS CLOUDY, LUMPY or DISCOLOURED.



8. Draw the total content of the vial into the syringe. If the 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.

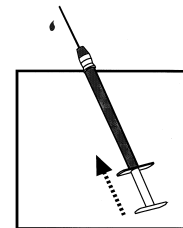


9. Withdraw the needle from the vial. Carefully recap the needle then twist it to detach the needle from the syringe. Discard the mixing needle into your puncture-proof container or lay it to the side. Carefully lay the syringe on a clean surface.

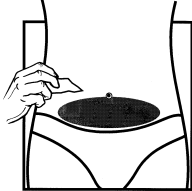

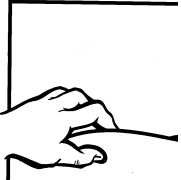



10. Take the needle for injection (grey) and remove the wrapping. Twist the needle onto the syringe so that it is tight. Carefully remove the cover of the needle by pulling it straight off.

11. Hold the syringe with the needle pointing upwards and gently flick the syringe if there are any visible air bubbles. The air bubbles will collect at the top of the syringe. If there are no air bubbles, or if there is no air space at the top of the syringe, pull the plunger back to allow for an air space of 0.1mL. Carefully replace the cap on the needle and lay the syringe down on the clean surface. Do not worry if you were unable to remove tiny air bubbles; they will do no harm. When you invert the syringe, the air space will be next to the plunger. This space will ensure that all of the medication has been injected. The air will remain in the needle.



Administration of the Medication

1. Choose an injection site on the lower abdominal area, preferably around, but at least one inch away from the belly button. If you are on a multiple dose (0.25 mg) regimen, choose a different injection site each day to minimize local irritation. Take a second alcohol wipe, clean the skin at the injection site and allow the alcohol to dry. Keep the alcohol wipe nearby. 
2. Pick up the syringe and remove the cap from the needle. Invert the syringe and hold as if “throwing a dart”. With your other hand, gently squeeze the skin together to make a little elevation at the injection site. Using a “dart like motion”, insert the needle at a 90 degree angle (you need very little force but quick action). 
3. Once the needle is inserted into the tissue all the way, inject the solution by pushing gently on the plunger with your thumb of the hand holding the syringe. Take as much time as you need to inject all the solution. 
4. Immediately withdraw the needle and clean the site with the clean side of the alcohol swab using a circular motion. If there is minor oozing you may need to apply a small amount of pressure for a minute.
5. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use into your disposal container or puncture-proof container with lid that fits firmly. 

SPECIAL ADVICE

What do you do if you have used too much CETROTIDE (cetrotirelix for injection)?

If you suspect that you may have taken more than the prescribed dose of this medicine, call your doctor or pharmacist or a poison control centre or emergency room of the nearest hospital immediately.

Possible Side Effects

As with all medication, there is a potential for side effects. Common side effects include: headache; injection site bruising, itching, swelling or redness; feeling sick (nausea).

Rare cases of allergic reactions can occur (warm, red skin, itching (often in your groin or armpits), red, itchy, raised areas (hives), runny nose, fast or uneven pulse, swelling of your

tongue and throat, sneezing, wheezing, serious difficulty breathing or dizziness). You may be having a possible serious, life-threatening allergic reaction to the medicine. If you notice any of the side effects above, stop using CETROTIDE (cetorelix for injection) and seek immediate medical attention.

During or following hormonal stimulation of the ovaries, ovarian hyperstimulation syndrome may develop. Ovarian hyperstimulation syndrome (OHSS) is a rare condition which occurs when too many follicles (part of the ovary that forms into an egg) grow and cause abdominal discomfort or pain, nausea, diarrhea and sometimes difficulty in breathing. In extreme cases hospitalization is necessary. OHSS is potentially very serious, but can be avoided by careful monitoring by your doctor.

Call your doctor if you have any side effects not mentioned in this leaflet or if you are unsure about the effect of this medicine.

Storage

How is CETROTIDE (cetorelix for injection) to be stored?

Store CETROTIDE (cetorelix for injection) in a cool dry place protected from excess moisture and heat, between 2 °C and 25°C. **Do not freeze.** Keep the packaged tray in the outer carton in order to protect it from light.

Store the medicine out of the reach of children.

How long may CETROTIDE (cetorelix for injection) be stored?

Do not use the CETROTIDE (cetorelix for injection) powder or the pre-filled syringe after the expiration date, which is printed on the labels and on the carton. After expiry, dispose of the vial and the syringe properly.

How long can you keep CETROTIDE (cetorelix for injection) after preparation of the solution?

The solution should be used immediately after preparation. Each vial and syringe should be used only once.

Important

This medicine was prescribed for your particular condition. Do not use it for another condition or give the medicine to others.