READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

CETROTIDE®
Cetrorelix for injection

Read this carefully before you start taking **CETROTIDE** 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 **CETROTIDE**.

What is CETROTIDE used for?
CETROTIDE stops your body from releasing an egg from your ovary (ovulation). It is used in assisted reproductive techniques to help you get pregnant.

How does CETROTIDE work?
CETROTIDE 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 your menstrual cycle. CETROTIDE controls ovulation so that it occurs at the best time for you to become pregnant.

What are the ingredients in CETROTIDE?
Medicinal ingredients: cetrorelix (as cetrorelix acetate)
Non-medicinal ingredients: mannitol

CETROTIDE comes in the following dosage forms:
Powder for solution, 0.25 mg.

Do not use CETROTIDE if you:
- are allergic to cetrorelix or mannitol, which are the ingredients in CETROTIDE
- are allergic to any component of the CETROTIDE container
- are allergic to medicines called peptide hormones
- are allergic to a hormone called gonadotropin-releasing hormone (GnRH) or to medicines called GnRH analogs
- are pregnant or think you might be pregnant
- are breastfeeding
- have moderate or severe liver problems
- have moderate or severe kidney problems

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CETROTIDE. Talk about any health conditions or problems you may have, including if you:
- are taking or have recently taken other medicines including those not requiring a prescription
- have an active allergy
- have had allergies in the past

Other warnings you should know about:

CETROTIDE will be given to you by a doctor with experience in assisted reproductive techniques.

Using CETROTIDE during more than one cycle:
Experience of using CETROTIDE during more than one cycle is limited. Your doctor will carefully look at the benefits and risks for you, if you need to use it during more than one cycle.

Ovarian Hyperstimulation Syndrome:
During or after you receive medicines that stimulate your ovaries, **ovarian hyperstimulation syndrome** can occur. With **ovarian hyperstimulation syndrome** your ovaries are enlarged and you may have abdominal bloating and pain. Although uncommon, this can be severe and life-threatening. In severe cases, hospitalization may be needed.

Birth defects and stillbirths:
Birth defects may be slightly higher in babies conceived by assisted reproductive technologies than those conceived naturally. In clinical trials where 949 women were treated with CETROTIDE, two stillbirths occurred.

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

Usual dose:

- The recommended dose of CETROTIDE is 0.25 mg once a day injected under your skin.
- It should be injected at the same time each day (every 24 hours).

How to take CETROTIDE:

- CETROTIDE is injected under your skin in your lower abdominal area.
- Your doctor should supervise your first injection.
- You may inject CETROTIDE on your own after your first injection if your doctor has told you how to inject it and what to do if you experience an allergic reaction.
- Your doctor will tell you on what days you should take CETROTIDE.
- Always use CETROTIDE exactly as your doctor has told you to.
- Check with your doctor if you are not sure how to take it.
- You must inject CETROTIDE in a different spot in your lower abdominal area each day if you inject it more than two days in a row.
- Use CETROTIDE immediately after you have prepared it for administration.

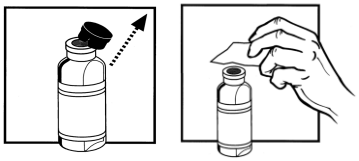
Preparation of CETROTIDE:

1. Clean your work surface with soap and water.

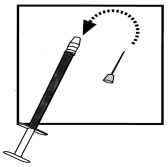
2. Wash your hands well with soap and water.

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

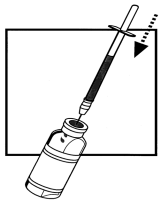
4. Flip off the plastic cover of the CETROTIDE vial. Clean the aluminum ring and rubber stopper with an alcohol wipe. Discard the alcohol wipe.



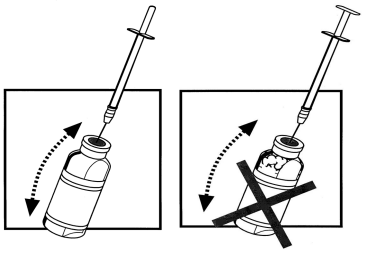
5. Take the needle for mixing (yellow mark) and remove the wrapping. Take the pre-filled syringe and remove the cover. Twist the needle onto the syringe so that it is tight. Carefully remove the cover of the needle by pulling it straight off.



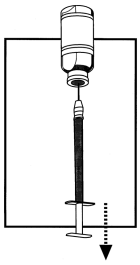
6. Push the needle through the center of the rubber stopper of the vial of CETROTIDE. Inject the water from the pre-filled syringe into the vial by slowly pushing down the plunger of the syringe. Dissolve CETROTIDE powder only with the water contained in the pre-filled syringe.



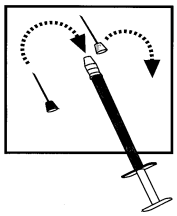
7. Without removing the needle from the vial, gently shake or rotate the vial until the solution is clear and without particles. Avoid forming bubbles. DO NOT USE IF SOLUTION APPEARS CLOUDY, LUMPY or DISCOLOURED.



8. Draw all of the liquid in 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. Be careful not to pull the plunger out of the syringe.

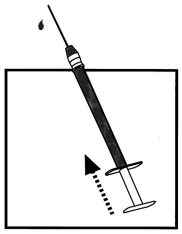


9. Withdraw the needle from the vial. Carefully put the cap back on the needle then twist it to detach the needle from the syringe. Discard the mixing needle into your puncture-proof container or lay it to the side. Carefully lay the syringe on a clean surface.



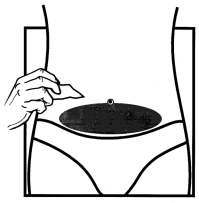
10. Take the needle for injection (grey) and remove the wrapping. Twist the needle onto the syringe so that it is tight. Carefully remove the cover of the needle by pulling it straight off.

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. Administer the solution immediately after preparation.

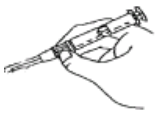


Administration of CETROTIDE:

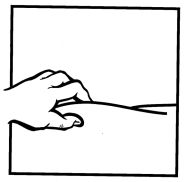
1. Choose an injection site on your lower abdominal area. It should be preferably around, but at least one inch away, from your belly button. Choose a different injection site each day to minimize local irritation. Take the second alcohol wipe, clean the skin at the injection site and allow the alcohol to dry. Keep the alcohol wipe nearby.



2. Pick up the syringe and remove the cap from the needle. Invert the syringe and hold it 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. Do this 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. Clean the injection site with the clean side of the alcohol wipe 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. Throw away the syringe and needles immediately after use. Discard them into a disposal container or puncture-proof container with a lid that fits firmly.

Overdose:

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

Missed Dose:
If you miss a dose of CETROTIDE do not take a double dose. Discuss with your doctor when you should receive your next dose. Check with your doctor if you have any questions about this.

What are possible side effects from using CETROTIDE?

These are not all the possible side effects you may feel when taking CETROTIDE. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- headache
- bruising, itching, swelling, pain or redness in your abdomen where you injected CETROTIDE
- feeling sick (nausea)

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	
COMMON			
Ovarian hyperstimulation syndrome (enlarged ovaries): abdominal bloating, diarrhea, nausea, pain in the abdomen, rapid weight gain, shortness of breath, vomiting.		√	
UNCOMMON			
Allergic reactions: dizziness, fast or uneven pulse, itching (often in your groin or armpits), red itchy raised areas on your skin (hives), runny nose, serious difficulty breathing, sneezing, swelling of your tongue and throat, warm red skin, wheezing.			√

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/adverse-reaction-reporting.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:
CETROTIDE should be stored by the patient between 2 – 8 °C (in a refrigerator). Storage at up to 30°C for a maximum of 3 months is allowed.

Do not freeze. Store it in a cool and dry place. Protect it from excess moisture and heat. Keep the container in the outer carton in order to protect it from light.

Store the medicine out of the reach and sight of children.

Do not use CETROTIDE or the pre-filled syringe after the expiry date printed on the labels and on the carton. After the expiry date, dispose of the vial and the syringe properly.

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

If you want more information about CETROTIDE:

- 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.html); http://www.emdserono.ca, or by calling MOMENTUM patient services program at 1-800-387-8479.

This leaflet was prepared by EMD Serono, a business of Merck KGaA, Darmstadt, Germany.

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