Frequently Asked Questions

What are the ingredients in CETROTIDE?

CETROTIDE contains cetrorelix acetate and mannitol as the non-active ingredient.

What is CETROTIDE used for?

CETROTIDE is used as part of the hormone treatment for ovarian stimulation. 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 the menstrual cycle. CETROTIDE allows the release of an egg to be controlled so that it occurs at an optimal time for pregnancy to occur.

How should I use CETROTIDE?

CETROTIDE should be injected under the skin 0.25 mg once daily.

CETROTIDE is administered on either stimulation day 5 (morning or evening) or day 6 (morning) and continued daily until the day of human chorionic gonadotropin (hCG) administration.

Who should not use CETROTIDE?

Before you use CETROTIDE, let your doctor know of any of the following: if you are taking or have recently taken other medications including those not requiring a prescription. Do not take CETROTIDE if you are allergic to cetrorelix acetate, mannitol, peptide hormones or to any component of the CETROTIDE container. Do not take CETROTIDE if you are pregnant, or think that you might be pregnant, or if you are breast-feeding; if you are allergic to a hormone called gonadotropin-releasing hormone (GnRH) or any other GnRH analogs (e.g., leuprolide acetate, goserelin acetate), or if you have moderate or severe liver or kidney problems.

What should I do if I take too much CETROTIDE?

If you suspect that you may have taken more than the prescribed dose of this medicine, contact your doctor immediately.

What should I do if I missed a dose?

If you miss a dose of CETROTIDE, 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 long can you keep CETROTIDE after preparation of the solution?

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

What are the possible side effects?

Common side effects include: headache, bruising, itching, swelling, pain or redness in your abdomen where you injected CETROTIDE, and feeling sick (nausea). In rare cases, allergic reactions can occur including 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, and wheezing. 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 and seek immediate medical attention.

During or following hormonal stimulation of the ovaries, ovarian hyperstimulation syndrome may develop. Ovarian hyperstimulation syndrome (OHSS) is a condition which occurs when too many follicles (part of the ovary that forms into an egg) grow and cause abdominal bloating, diarrhea, nausea, pain in the abdomen, rapid weight gain, shortness of breath, and vomiting. In serious cases, hospitalization is necessary. OHSS is potentially very serious, but can usually 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.

What are some important points to remember?

- Store CETROTIDE between 2–8°C (in a refrigerator).
- Storage at up to 30°C for a maximum of 3 months is allowed.
- Protect CETROTIDE from excess moisture and heat. Do not freeze.
- Keep the packaged tray in the outer carton to protect it from light.
- Always check the expiry date on the labels and on the carton before use – never use expired CETROTIDE or expired pre-filled syringe.
- After expiry, dispose of the vial and the syringe properly.
- Store the medicine out of the reach of children.
- This medicine was prescribed for your particular condition.
 Do not use it for another condition or give the medicine to others.
- For additional information, please refer to the package insert that came with your medication, or the latest approved product monograph.

Looking for support?

You are not alone.



MOMENTUM is a free and confidential patient services program that offers customized support, including injection assistance – available to individuals using EMD Serono fertility products





1-800-387-8479

fertility.mymomentum.ca

Call *MOMENTUM* between the hours of 8:00 a.m. and 8:00 p.m. (Eastern Time), Monday to Friday.

MOMENTUM is available 24 hours a day, 7 days a week for urgent inquiries that cannot wait until the following business day. Simply leave your name, reason for calling, and phone number, and a registered nurse will return your call in a timely manner.

MOMENTUM will not comment on individual diagnosis or treatment questions, or laboratory results. You should discuss those with your healthcare provider. MOMENTUM is a source of educational support sponsored by EMD Serono, Canada and is not intended to replace discussions with your healthcare provider.



CETROTIDE Product Monograph. EMD Serono, July 2018.

CETROTIDE® is a registered trademark of Zentaris IVF GmbH, Germany. Importer & Distributor: EMD Serono, a division of EMD Inc., Canada A business of Merck KGaA, Darmstadt, Germany 2695 North Sheridan Way, Suite 200, Mississauga, Ontario L5K 2N6 Canada



MEMBER OF INNOVATIVE MEDICINES CANADA

CA/CET/0818/0002

RH0054E





ADMINISTRATION AND STORAGE INSTRUCTIONS



CETROTIDE is available in:

• 0.25 mg







Step 1

Flip off the plastic cover of the vial of CETROTIDE.

Before you begin:

2. Wash hands well with soap and water.

 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



Step 2

Wipe the aluminum ring and rubber stopper with an alcohol wipe.

Discard the alcohol wipe.



Step 3

Take the pre-filled syringe of diluent and remove the cover.



Step 4

Remove the wrapping on the yellow mixing needle.

Twist the needle onto the pre-filled syringe so that it is tight.

Carefully remove the needle cover.



Step 5

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 only with the water contained in the pre-filled syringe.



Step 6

Without removing the needle from the vial, gently rotate the vial until the solution is clear and without particles.

Avoid forming bubbles.

IMPORTANT: Do not use if solution appears cloudy, lumpy or discoloured.



Step 7

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.



Step 8

Withdraw the needle from the vial. Carefully recap the needle.



Step 9

Twist to detach the needle from the syringe.

Discard the mixing needle into a sharps container. Carefully lay the syringe on a clean surface.



Step 10

Remove the wrapping on the grey injection needle. Twist the needle onto the syringe so that it is tight.

Carefully remove the cover of the needle by pulling it straight off.



Step 11

a. Hold the syringe with the needle pointing upwards and gently flick the syringe if there are any visible air bubbles.

b. 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 0.1 mL

Carefully replace the cap and lay the syringe on a clean surface.

IMPORTANT: It is important to have an air space in your syringe before you inject. This will ensure that all the medication has been injected.



Step 12

Choose an injection site: CETROTIDE is for injection under the skin of the lower abdominal wall.

Select a different injection site each day to minimize local irritation.



Step 13

Clean the skin at the injection site using an alcohol wipe and allow the alcohol to dry.

Keep the alcohol wipe nearby.





Step 15

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.



Step 16

Using a "dart like motion", insert the needle at a 90° angle.

IMPORTANT: To inject, you need very little force but quick action.



Step 17

Once the needle is inserted into the tissue all the way, inject the solution by pushing gently on the plunger with the hand holding the syringe.

Take as much time as you need to inject all the solution.



Step 18

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.

Dispose of the syringe and needles immediately after use into a sharps container.

