



Steps for Self-Injection of Cetrotide®



Reassurance matters

For nearly 20 years, Cetrotide® has been used in fertility treatment.

INDICATIONS

What are the uses of Cetrotide®?

Cetrotide® blocks the effects of a natural hormone, called gonadotropin-releasing hormone (GnRH). GnRH controls the secretion of another hormone, called luteinizing hormone (LH), which induces ovulation during the menstrual cycle.

Cetrotide® blocks undesirable premature ovulation. Premature ovulation may lead to eggs that are not available for egg retrieval.

IMPORTANT RISK INFORMATION

Who should not use Cetrotide®?

- Patients that are allergic to cetrotide acetate, mannitol, or exogenous peptide hormones (medicines similar to Cetrotide®) should not use Cetrotide®.
- If you have had severe allergic reactions to any drugs in a previous IVF cycle, tell your doctor.
- Cetrotide® should not be used in patients who are pregnant, think they might be pregnant, or are breastfeeding.
- Cetrotide® should not be used in patients with kidney disease.

How to use Cetrotide®

Do not inject Cetrotide® at home until your healthcare provider has taught you the right way to inject it.

Cetrotide® is for injection under the skin of the lower abdomen area, staying at least one inch away from the belly button. Choose a different injection site each day to minimize irritation.

Please read the following instructions carefully.

PREP: Before you get started



Cetrotide® must be stored in the refrigerator between 36-46°F. Do not freeze. Keep the packaged tray in the outer carton in order to protect it from light.



Wash your hands with soap and water to keep the things you use as clean as possible.



Gather everything you need on a clean, flat surface:

- one vial of powder
- one pre-filled syringe with sterile water (diluent)
- one needle with a **yellow** mark – for injecting the sterile water into the vial and drawing the mixed medicine out from the vial
- one needle with a **gray** mark – for injecting the medicine into your abdomen
- two alcohol swabs

Before starting Cetrotide®, tell your healthcare professional about all your medical conditions. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

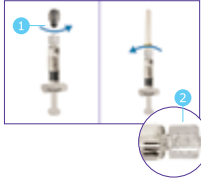
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. Or contact EMD Serono at 1-800-283-8088.

Please see Important Risk Information continued on page 2 and accompanying Full Prescribing Information.

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. It is important to **gently** twist the **1 removable plastic cover** from the syringe to be able to connect AND disconnect the needle(s). Pulling or twisting with too much force may disconnect the **2 affixed acrylic connection tip** and compromise the contents of the syringe.



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 3 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.

Preparing the injection site and your 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 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 and allow alcohol to dry. Inject the prescribed dose as directed by your doctor, nurse or pharmacist.

Injecting your medicine



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.



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 (put the covers on the needles to avoid injury). A medical waste container should be used for disposal.

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

Do not reuse or share syringes or needles

IMPORTANT RISK INFORMATION (continued)

What is the most important information I should know before starting Cetrotide®?

- Your doctor will confirm you are not pregnant.

What are the possible side effects of Cetrotide®?

Cetrotide® may cause serious side effects including:

- Allergic reactions including anaphylactic reaction with the first dose. Treatment with Cetrotide® is not advised in women with severe allergic conditions.
- Your doctor should review with you the risks and benefits of using Cetrotide®.
- It is not known if Cetrotide® is excreted in human milk. Because the effects of Cetrotide® on nursing mothers or the nursing infant are not known, do not use Cetrotide® if you are breastfeeding.

Common side effects of using Cetrotide® include:

- Mild and short-lasting reactions may occur at the injection site like reddening, itching, and swelling. Nausea and headache have also been reported.

Call your doctor if you have any other side effect or if you are unsure about the effect of this medicine.

These are not all the possible side effects of Cetrotide®. For more information, read the product labeling, and ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Full Prescribing Information and Patient Leaflet for Cetrotide® provided with this tear pad and in your product carton, or visit online.

FAQs

How do I properly dispose of medicine products?

Used needles, vial, and syringe should be discarded in an FDA-cleared sharps disposal container immediately after use.

If you do not have a sharps container, do not throw away loose needles and vials in your household trashcan.

Instead, use a container that is:

- made of heavy-duty plastic
- able to be closed with a tight-fitting, puncture-resistant lid
- upright and stable during use
- leak resistant
- properly labeled to warn of hazardous waste inside the container

For more information, visit www.fda.gov/safesharpsdisposal.

What do I do if I have used too much Cetrotide®?

In case of overdosage, contact your doctor immediately to check whether an adjustment of the further ovarian stimulation procedure is required.

Can I still use my medication if I left it outside in a car during hot or cold weather?

Cetrotide® must be stored away from light and in the refrigerator between 36°F and 46°F.

For more information about storing your medication, call Fertility LifeLines™ support at 1-866-538-7879 or contact your healthcare provider.



MORE SUPPORT

For more support materials, visit EMDSeronoFertility.com.