

CETROTIDE® POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Cetorelix Acetate (0.25mg)

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What Cetrotide is used for

Cetrotide is used to prevent premature ovulation (the release of an egg from the ovary) in women undergoing an assisted reproduction cycle, such as in vitro fertilization (IVF).

Ovulation that is too early, before the egg has fully matured, is undesirable during hormone treatment for ovarian stimulation, because only mature egg cells are suitable for fertilization.

How Cetrotide works

The active substance in Cetrotide, cetorelix, blocks the effects of a natural hormone called luteinising-hormone-releasing hormone (LHRH). LHRH controls the production and release of another hormone called luteinising hormone (LH), which causes ovulation during the menstrual cycle. During fertility treatment, ovarian stimulation is normally used to make the ovaries produce more eggs. By blocking the effect of LHRH, Cetrotide stops the production of LH, and therefore prevents premature ovulation, which can result in the release of eggs that are immature and unsuitable for use in techniques such as in vitro fertilisation (IVF).

Before you use Cetrotide

- When you must not use it

Do not use Cetrotide if you have an allergy to:

- Cetorelix acetate
- Mannitol

- Exogenous peptide hormones (medicines similar to Cetrotide).

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin.

Do not use Cetrotide if you are or have any of the following conditions:

- severe kidney disease
- you are pregnant or suspect that you might be pregnant
- breastfeeding
- Severe allergic conditions

Do not use Cetrotide after the expiry date printed on the packaging has passed, or if the packaging is torn or shows signs of tampering.

If your medicine has expired or is damaged, return it to your pharmacist or clinic for disposal.

If you are not sure whether you should start using Cetrotide, talk to your doctor.

- Before you start to use it

Cetrotide should only be prescribed by a specialist experienced in this field. Tell your doctor or pharmacist if you have allergies to any foods, dyes, preservatives, or any other medicines.

A condition called Ovarian Hyperstimulation Syndrome (OHSS) may occur during or following a controlled ovarian stimulation. This is when the ovaries overreact to the hormone treatment and become too large. Your doctor will monitor your treatment and advise you what to do. Talk to your doctor about any concerns you may have before undergoing treatment or before you start using Cetrotide.

- Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements, or natural therapies you buy without prescription from your pharmacy, supermarket, naturopath or health food shop.

There is a possibility that some medicines and Cetrotide may interfere with each other.

How to use Cetrotide

Your first injection of Cetrotide should be given by your doctor or nurse. You should remain under their supervision for 30 minutes after this injection in case of allergic reaction. After the first injection you may be required to inject Cetrotide yourself. Your doctor or nurse will provide you with appropriate instructions, including the signs, symptoms, and treatment of allergic reactions.

Do not self-inject until you are sure of how to do it.

Read carefully the Instruction for Use provided in the pack before commencing injections.

Cetrotide is usually given under the skin of the lower abdominal wall, preferably around the navel. The injection site should be changed daily to minimize local irritation. Do not inject into any areas in which you feel lumps, firm knots, depressions, pain, or discolouration. Talk to your doctor if you find anything unusual when injecting.

- How much to use

Your doctor will tell you how much Cetrotide to use and when to inject it.

- When to use it

The contents of one vial of Cetrotide 0.25mg are given once daily, at 24-hour intervals, either in the morning or in the evening.

- How long to use it

It is given over several days. Your doctor or pharmacist will advise you on which days you should use it.

- If you forget to use it

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject a double dose on any day.

Ask your doctor if you are not sure what to do or you are having trouble remembering to inject your medicine.

- If you use too much (overdose)

Immediately contact your doctor if you are concerned that you have given yourself too much or someone else has injected themselves with Cetrotide

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using Cetrotide

- Things you must do

See your doctor regularly and keep all your doctor's appointments so your progress can be checked.

Your doctor will monitor you closely throughout your treatment.

Tell your doctor immediately if you become pregnant while using Cetrotide.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Cetrotide.

If you plan to have surgery, tell your doctor or dentist that you are using Cetrotide.

Tell all doctors, dentists and pharmacists who are treating you that you are using Cetrotide.

- Thing you must not do

Do not stop using Cetrotide without telling your doctor.

Do not give this medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Cetrotide is not expected to impair your ability to drive or to operate machinery.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may not experience any of them.

Ask your doctor, nurse, or pharmacist to answer any questions you may have.

Tell your doctor, nurse, or pharmacist if you notice any of the following and they worry you:

- redness, itching, swelling of the injection site (these are usually mild and short-lasting)
- headache
- feeling sick (nausea)

Tell your doctor, nurse, or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

Storage and Disposal of Cetrotide

- Storage

Store in a refrigerator (2°C to 8°C).

Do not freeze or place next to the freezer compartment or a freezer pack. Keep the container in the original carton in order to protect from light.

You may store Cetrotide not above 30°C for one single period of up to a maximum of 3 months.

This medicinal product must be allowed to reach room temperature prior to injection. It should be removed from the refrigerator approximately 30 minutes before use. Inject the reconstituted Cetrotide as soon as it is prepared. Cetrotide should only be reconstituted with the solvent provided, using a gentle, swirling motion. Vigorous shaking with bubble formation should be avoided.

Do not use the dissolved solution if it contains particles or is not clear.

Use each vial and syringe only once. Use a new vial and syringe for each dose.

The entire content of the vial should be withdrawn to ensure delivery of complete dose.

Do not leave it in the car.

Keep it where children cannot reach it.

Do not store it or any other medicine in the bathroom or near a sink.

- Disposal

If you are self-injecting, discard all sharps into a disposal unit.

If you have any Cetrotide that has expired or is left over from your treatment, refer this to your clinic.

Product description

- What it looks like

Cetrotide is a sterile white powder in clear and colourless solution.

Cetrotide is available in one presentation: 0.25mg in packs of one or seven vials.

Each pack contains:

- Cetrotide 0.25mg powder in a glass vial
- Pre-filled syringe(s) with clear and colourless solvent (Water for Injections) for dissolving the powder before injection
- Injection needle(s), with a yellow mark, to be used for injecting the solvent into the vial and withdrawing the solution from the vial
- Injection needle(s), with a grey mark, to be used for injecting the solution
- Alcohol swabs for cleaning purposes.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient: Cetrorelix acetate

- Inactive ingredient: Mannitol

- MAL Number

MAL20021353ACZ

MAL16115035ACSZ

Manufacturer

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Product Registration Holder

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How Should Cetrotide 0.25 mg be used

This section tells you how to mix the powder and the sterile water (solvent) together and then how to inject your medicine.

You may self-administer Cetrotide 0.25 mg after appropriate instruction from your doctor.

This medicine is only for you – do not let anyone else use it.

Cetrotide 0.25 mg is for injection under the skin of the lower abdominal wall, preferably around the navel. To minimize local irritation, please select a different injection site each day.

Dissolve Cetrotide 0.25 mg powder only with the water contained in the pre-filled syringe. Do not use a Cetrotide 0.25 mg solution if it contains particles or if it is not clear.

Before you administer yourself, please read the following instructions carefully

1. This medicine must be at room temperature prior to injection. Remove from the refrigerator approximately 30 minutes before use.

2. Wash your hands

- It is important that your hands and the things you use are as clean as possible.

3. Lay out everything you need on a clean surface:

- one vial of powder
- one pre-filled syringe with sterile water (solvent)
- one needle with a **yellow** mark – for injecting the sterile water into the vial and drawing the made-up medicine out from the vial
- one needle with a **grey** mark – for injecting the medicine into your belly

- two alcohol swabs

Mixing the powder and water to make up your medicine

1. Remove the cap from the vial

- There will be a rubber stopper underneath – keep this in the vial.
- Wipe the rubber stopper and metal ring with your first alcohol swab.

2. Adding the water from the pre-filled syringe to the powder in the vial

- Unwrap the needle with the **yellow** mark on it.
- Remove the cap from the pre-filled syringe and screw the yellow needle onto it. Remove the cap from the needle.
- Push the yellow needle through the centre of the rubber stopper of the vial.
- Slowly push in the plunger of the syringe to inject the water into the vial. Do not use any other sort of water.
- Leave the syringe in the rubber stopper.

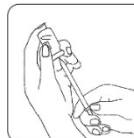


3. Mixing the powder and water in the vial

- 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.

4. Re-filling the syringe with the medicine from the vial

- Turn the vial upside down. Then, gently pull back the plunger, in order to draw the medicine from the vial into the syringe.



Take care not to pull out completely the plunger with the attached plunger stopper. In case you pulled out the plunger with the plunger stopper by mistake, make sure to discard the dose as sterility will be lost, and prepare a new dose (and restart from step 1).

- If any medicine is left in the vial, pull out the yellow needle until the end of the needle is just inside the rubber stopper. If you look from the side through the gap in the rubber stopper, you can control the movement of the needle and the liquid.
- Make sure that you collect all of your medicine from the vial.
- Put the cap back on the yellow needle. Unscrew the yellow needle from the syringe and lay down the syringe.

Preparing the injection site and injecting your medicine

1. Removing air bubbles

- Unwrap the needle with the **grey** mark on it. Screw the grey needle onto the syringe and remove the cap from the grey needle.
- Hold the syringe with the grey needle pointing upwards and check for any air bubbles.
- To remove air bubbles, gently flick the syringe until all the air collects at the top – then slowly push the plunger in until the air bubbles are gone.
- Do not touch the grey needle and do not let the needle touch any surface.

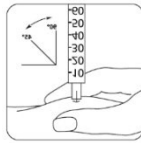


2. Clean the injection site

- Choose an injection site on your belly. It is best around the belly button (navel). To reduce skin irritation, select a different part of your belly each day.
- Clean the skin at your chosen injection site with your second alcohol swab - use a circular motion.

3. Piercing your skin

- Hold the syringe in one hand – like you would hold a pencil.
- Gently pinch up the skin around where you are going to inject and hold this firmly with your other hand.
- Slowly push the grey needle completely into your skin at an angle of about 45 to 90 degrees – then let go of your skin.



4. Injecting your medicine

- Gently pull back the plunger of the syringe. If blood appears, follow Step 5 below.
- If no blood appears, **slowly** push the plunger in to inject your medicine.
- When the syringe is empty, take out the grey needle slowly at the same angle.
- Use your second alcohol swab to gently apply pressure where you have just injected.

5. If blood appears:

- take out the grey needle slowly at the same angle
- use your second alcohol swab to gently apply pressure where you have just pierced your skin
- empty your medicine into a sink and follow Step 6 below
- wash your hands and start again with a new vial and pre-filled syringe.

6. Disposal

- Use each needle, vial and syringe only once.
- Put the cap back on the needles so that they are safe to be thrown away.
- Ask your pharmacist how to safely dispose of used needles, vial and syringe.