

CETROTIDE[®] INJECTION

Cetrorelix 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, cetrorelix, 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:

- Cetrorelix 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 have, or have had, any of the following medical conditions:

- liver disease
 - kidney disease.
- Do not use Cetrotide if
- you have already reached menopause.
 - you are pregnant or suspect that you might be pregnant.

Do not breastfeed while you are using Cetrotide.

It is not known whether Cetrotide passes into breast milk. The potential effects on breastfed infants are not known.

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 over react 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

If you have any of the following severe symptoms, contact your doctor immediately:

- nausea
- vomiting
- diarrhoea
- stomach pain or discomfort.

These may be signs of overstimulation of the ovaries which requires urgent attention.

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Cetrotide

- Storage

Store in a refrigerator (2°C to 8°C). 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.

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.

The final solution does not contain a preservative.

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.

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 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

MAL20021353AZ

Manufacturer

Baxter Oncology GmbH (D-33790
Halle), Germany

Product Registration Holder

Merck Sdn Bhd (178145-V)
Level 3, Menara Sunway Annexe,
Jalan Lagoon Timur
Bandar Sunway
46150, Petaling Jaya
Selangor Darul Ehsan

Date of Revision:

01/07/2017

Serial Number

BPFK(R4/1)070617/00125

How Should Cetrotide ® 0.25 mg be used

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

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

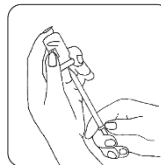
1. Wash your hands thoroughly with soap and water. It is important that your hands and all items you use are as clean as possible.
2. Lay out on a clean flat surface everything you need (one vial of powder, one pre-filled syringe, one injection needle with a yellow mark, one injection needle with a grey mark and two alcohol swabs).
3. Flip off the plastic cover of the vial. Wipe the aluminium ring and the rubber stopper with an alcohol swab.
4. Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Twist the needle on the syringe and remove the cover of the needle.
5. Push the needle through the center of the rubber stopper of the vial. Inject the water into the vial by slowly



pushing the plunger of the syringe.

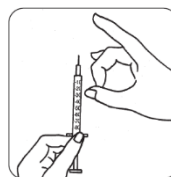
6. Leave the syringe in the vial. Gently agitate the vial until the solution is clear and without residues. Avoid forming bubbles during dissolution

7. Draw the whole contents of the vial into the syringe. If solution is left in the vial, turn the vial upside-down, slowly and carefully pull the needle out of the stopper, until the opening of the needle is just inside the stopper. If you look from 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.



8. Detach the syringe from the needle and lay down the syringe. Take the injection needle with the grey mark and remove its wrapping. Twist the new needle on the syringe and remove the cover of the needle.

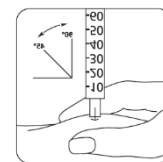
9. Invert the syringe and push the plunger until all air bubbles have been expelled. Do not touch the needle or allow the needle to touch any surface.



10. Choose an injection site on the stomach, preferably around, but at least 2 cm away from the navel. If you are on a multiple dose (CETROTIDE 0.25 mg) course of injections choose a different site each day to reduce the local irritation. Take the second alcohol swab and clean the skin at the injection site and allow the alcohol to dry. Hold the

syringe in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.

11. Hold the syringe as you would hold a pencil, insert the needle completely into the skin at an angle of about 45 degrees.



12. Once the needle has been inserted completely, release your grasp of the skin.
13. Pull back gently the plunger of the syringe. If blood appears continue as described in step 14. If no blood appears, inject the solution slowly by pushing the plunger gently forward. After all of the solution is injected, withdraw the needle slowly, applying gentle pressure with the alcohol swab on the skin where the needle was inserted. Withdraw the needle at the same angle as it was inserted.

14. If blood appears, withdraw the needle with the syringe and gently apply pressure to the injection site. Do not use this solution but empty the syringe in a sink. Start again with step 1.

15. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use (put the covers on the needles to avoid injury).