



Package leaflet: Information for the user

Cetrotide® 0.25 mg

powder and solvent for solution for injection

Cetrorelix

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cetrotide is and what it is used for
 2. What you need to know before you use Cetrotide
 3. How to use Cetrotide
 4. Possible side effects
 5. How to store Cetrotide
 6. Contents of the pack and other information
- How to mix and inject Cetrotide

1. What Cetrotide is and what it is used for

What Cetrotide is

Cetrotide contains a medicine called 'cetrorelix'. This medicine stops your body from releasing an egg from your ovary (ovulation) during your menstrual cycle. Cetrotide belongs to a group of medicines called 'anti-gonadotropin-releasing hormones'.

What Cetrotide is used for

Cetrotide is one of the medicines used during 'assisted reproductive techniques' to help you get pregnant. It stops eggs being released straight away. This is because if the eggs are released too early (premature ovulation) it may not be possible for your doctor to collect them.

How Cetrotide works

Cetrotide blocks a natural hormone in your body called LHRH ('luteinising hormone releasing hormone').

- LHRH controls another hormone, called LH ('luteinising hormone').
- LH stimulates ovulation during your menstrual cycle.

This means that Cetrotide stops the chain of events that leads to an egg being released from your ovary. When your eggs are ready to be collected, another medicine will be given to you that will release them (ovulation induction).

2. What you need to know before you use Cetrotide

Do not use Cetrotide

- if you are allergic to cetrorelix or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines similar to Cetrotide (any other peptide hormones).
- if you are pregnant or breast-feeding.
- if you have severe kidney disease.

Do not use Cetrotide if any of the above applies to you. If you are not sure, talk to your doctor before using this medicine.

Warnings and precautions

Allergies

Tell your doctor before using Cetrotide if you have an active allergy or have had allergies in the past.

Ovarian Hyperstimulation Syndrome (OHSS)

Cetrotide is used together with other medicines that stimulate your ovaries to develop more eggs ready to be released. During or after you receive these medicines, you may develop OHSS. This is when your follicles develop too much and become large cysts.

For possible signs to look out for and what to do if this happens see section 4 '*Possible side effects*'.

Using Cetrotide during more than one cycle

Experience of using Cetrotide during more than one cycle is small. Your doctor will carefully look at the benefits and risks for you, if you need to have Cetrotide during more than one cycle.

Liver disease

Tell your doctor before using Cetrotide if you have a liver disease. Cetrotide has not been investigated in patients with hepatic disease.

Kidney disease

Tell your doctor before using Cetrotide if you have a kidney disease. Cetrotide has not been investigated in patients with kidney disease.

Children and adolescents

Cetrotide is not indicated for the use in children and adolescents.

Other medicines and Cetrotide

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

Do not use Cetrotide if you are pregnant, think you may be pregnant, or if you are breast-feeding.

Driving and using machines

Cetrotide is not expected to affect your ability to drive and use machines.

3. How to use Cetrotide

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Using this medicine

This medicine is only for injection just under the skin of your belly (subcutaneous). To reduce skin irritation, select a different part of your belly each day.

- Your doctor must supervise your first injection. Your doctor or nurse will show you how to prepare and inject the medicine.
- You can carry out the following injections yourself as long as your doctor has made you aware of the symptoms that may indicate allergy and of the possibly serious or life-threatening consequences that would need immediate treatment (see section 4 '*Possible side effects*').
- Please carefully read and follow the instructions at the end of this leaflet called '*How to mix and inject Cetrotide*'.
- You start by using another medicine on day 1 of your treatment cycle. You then start using Cetrotide a few days later. (See next section '*How much to use*').

How much to use

Inject the contents of one vial (0.25 mg Cetrotide) once each day. It is best to use the medicine at the same time each day, leaving 24 hours between each dose.

You can choose to inject every morning **or** every evening.

- If you are injecting every morning: Start your injections on day 5 or 6 of the treatment cycle. Based on your ovarian response, your doctor may decide to start on another day. Your doctor will tell you the exact date and time. You will keep using this medicine up until and including the morning that your eggs are collected (ovulation induction).

OR

- If you are injecting every evening: Start your injections on day 5 of the treatment cycle. Based on your ovarian response, your doctor may decide to start on another day. Your doctor will tell you the exact date and time. You will keep using this medicine up until and including the evening before your eggs are collected (ovulation induction).

If you use more Cetrotide than you should

Bad effects are not expected if you accidentally inject more of this medicine than you should. The effect of the medicine will last for longer. No specific measures are usually required.

If you forget to use Cetrotide

- If you forget a dose, inject it as soon as you remember and talk to your doctor.
- Do not inject a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

- Warm, red skin, itching (often in your groin or armpits), red, itchy, raised areas (hives), runny nose, fast or uneven pulse, swelling of your tongue and throat, sneezing, wheezing or serious difficulty breathing, or dizziness. You may be having a possible serious, life-threatening allergic reaction to the medicine. This is uncommon (may affect up to 1 in 100 women).

If you notice any of the side effects above, stop using Cetrotide and contact your doctor immediately.

Ovarian Hyperstimulation Syndrome (OHSS)

This may occur due to the other medicines that you are using to stimulate your ovaries.

- Lower abdominal pain together with feeling sick (nausea) or being sick (vomiting) may be the symptoms of OHSS. This may indicate that the ovaries over-reacted to the treatment and that large ovarian cysts developed. This event is common (may affect up to 1 in 10 women).
- The OHSS may become severe with clearly enlarged ovaries, decreased urine production, weight gain, difficulty breathing or fluid in your stomach or chest. This event is uncommon (may affect up to 1 in 100 women).

If you notice any of the side effects above, contact your doctor immediately.

Other side effects

Common (may affect up to 1 in 10 women):

- Mild and short-lasting skin irritation may occur at the injection site like redness, itching or swelling.

Uncommon (may affect up to 1 in 100 women):

- Feeling sick (nausea)
- Headache.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetrotide

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, vial and pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze or place next to the freezer compartment or a freezer pack.

Store in the original package in order to protect from light.

The unopened product may be stored in the original package at room temperature (not above 30°C) for up to three months.

The solution should be used immediately after preparation.

Do not use this medicine if you notice that the white powder in the vial has changed in appearance. Do not use the prepared solution in the vial if it is not clear and colourless or if it has particles in it.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cetrotide contains

- The active substance is cetrorelix. Each vial contains 0.25 mg cetrorelix (as acetate).
- The other ingredients are:
 - In the powder: mannitol.
 - In the solvent: water for injections.

What Cetrotide looks like and contents of the pack

Cetrotide is a powder and solvent for solution for injection. The white powder comes in a glass vial with a rubber stopper. The solvent is a clear and colourless solution in a pre-filled syringe.

The powder vial contains 0.25 mg cetrorelix and the pre-filled syringe contains 1 ml solvent.

It is available in packs of 1 vial and 1 pre-filled syringe or 7 vials and 7 pre-filled syringes (not all pack sizes may be marketed).

For each vial, the pack also contains:

- 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 for cleaning

HOW TO MIX AND INJECT CETROTIDE

- This section tells you how to mix the powder and the sterile water (solvent) together and then how to inject your medicine.
- Before starting to use this medicine, please read these instructions the whole way through first.
- This medicine is only for you – do not let anyone else use it.
- Use each needle, vial and syringe only once.

Before you start

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.

Marketing Authorisation Holder

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Manufacturer

Baxter Oncology GmbH, Kantstrasse 2, D-33790 Halle, Germany

Batch releasing site

Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt, Germany

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This is a medicine

- A medicine is a product which affects your health and its consumption, contrary to instructions, is dangerous for you.
- Closely follow your doctor's prescription, the method of use and the instructions of the pharmacist who sold the product.
- Your doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the period of treatment prescribed without your doctor's permission.
- Do not repeat the same prescription without consulting your doctor.

Keep medicines out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists