

Cetrolimed

Powder and solvent for solution for subcutaneous injection

Active ingredient:

Each vial with powder contains: cetorelix (as acetate) 0.25 mg
Solvent: sterile water for injection

For inactive ingredients and allergens in the preparation – see section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist. Keep this leaflet; you may need to read it again. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Cetrolimed is one of the preparations used during "assisted reproductive techniques" to help you become pregnant. It stops the immediate release of oocytes, because if the oocytes are released too early (premature ovulation), it may not be possible for your doctor to collect them.

Therapeutic class: anti-gonadotropin-releasing hormones.

Cetrolimed contains a medicine called "cetorelix acetate". Cetrolimed inhibits the activity of the natural hormone called luteinizing hormone-releasing hormone (LHRH).

- LHRH – a hormone which regulates another hormone, called luteinizing hormone (LH).
- LH – luteinizing hormone, which stimulates ovulation during the menstrual cycle.

Essentially, Cetrolimed stops the chain of events that leads to the release of an oocyte from the ovary. When the oocytes are ready for collection, you will be given another preparation that will cause them to be released (ovulation induction).

2. Before using the medicine

Do not use Cetrolimed if:

- You are sensitive (allergic) to the active ingredient (cetorelix) or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- You are sensitive (allergic) to medicines similar to Cetrolimed (any other peptide hormone).
- You are pregnant or breastfeeding.
- You have a severe kidney disease.

Do not use Cetrolimed if any of the conditions listed above apply to you. If you are uncertain, consult the doctor before using the medicine.

Special warnings regarding the use of the medicine

Allergies

Before treatment with Cetrolimed, inform the doctor about any existing or past allergic effects.

Ovarian hyper stimulation syndrome (OHSS)

Cetrolimed is used in combination with other medicines that stimulate your ovaries, in order to develop more oocytes ready to be released. During or after receiving these medicines, you may develop ovarian hyper stimulation syndrome (OHSS). This is a situation in which the follicles develop too much and become large cysts. For possible signs that require follow-up and what to do in such a case, please see section 4 "Side effects".

Use of Cetrolimed in more than one treatment cycle

Your doctor will weigh the benefit against the risk in your case, if it is necessary to use Cetrolimed in more than one treatment cycle.

This is due to the little experience with the use of Cetrolimed in more than one treatment cycle.

Liver disease

Before using Cetrolimed, tell the doctor if you have a liver disease. Cetrolimed has not been tested in patients with a liver disease.

Kidney disease

Before using Cetrolimed, tell the doctor if you have a kidney disease. Cetrolimed has not been tested in patients with a kidney disease.

Children and adolescents

Cetrolimed is not indicated for use in children and adolescents.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Pregnancy and breastfeeding

Do not use Cetrolimed if you are pregnant, think you might be pregnant or if you are breastfeeding.

Driving and operating machinery

This medicine is not expected to affect your ability to drive or operate machinery.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Using the medicine

The preparation is intended for subcutaneous injection into your abdomen only. Choose a different injection site in the abdomen each day, to reduce skin irritation.

- The first injection should be performed under the doctor's supervision. The doctor or nurse will show you how to prepare and inject the medicine.
- Subsequently, you will be able to inject yourself after receiving an explanation from the doctor regarding symptoms that indicate an allergic reaction, which can be severe or life-threatening and which requires immediate treatment (see section 4 "Side effects").
- Carefully read and follow the instructions in the last part of this leaflet, which is called "Instructions for dissolving and injecting Cetrolimed".
- On the first day of the treatment cycle, you will start using another preparation. Start using Cetrolimed a few days later (see in the next section "How much to use").

How much to use

Inject the content of one Cetrolimed vial, once a day. It is advisable to use the preparation at the same time each day, with a 24-hour interval between one injection and the next.

You can choose to inject every morning or every evening.

- If you inject every morning: start your injections on the fifth or sixth day of the treatment cycle.
Your doctor will tell you the exact day and time. Continue using the preparation until your oocytes are collected, including on the morning of oocyte collection (ovulation induction).

Or

- If you inject every evening: start your injections on the fifth day of the treatment cycle.
Your doctor will tell you the exact day and time. Continue using the preparation until your oocytes are collected, including the evening before oocyte collection (ovulation induction).

Do not exceed the recommended dose.

If you accidentally took a higher dosage

No adverse effects are expected if you accidentally inject more Cetrolimed than the amount you need. The effect of the preparation will last for longer. There is usually no need to take any specific measures.

If you forgot to take the medicine

- If you forgot a dose, inject it as soon as you remember and inform your doctor.
- Do not inject a double dose in order to compensate for the forgotten dose.

Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Cetrolimed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to a doctor immediately if you notice any of the following side effects:

Allergic reactions

Heat sensation, skin redness, itching (often in the groin area or armpit), red, itchy, raised areas (hives), runny nose, fast or irregular heartbeat, swelling of the tongue and throat, sneezing, wheezing or serious breathing difficulties or dizziness. You may be having an allergic reaction, which may be serious and life-threatening. These effects are uncommon (may affect up to 1 out of 100 patients).

Refer to a doctor immediately if you notice any of the following side effects:

Ovarian hyper stimulation syndrome (OHSS)

This effect may occur because you are using other medicines to stimulate the ovaries.

- Pain in the lower abdomen together with nausea or vomiting may be symptoms of hyperreactivity of the ovary. This may indicate that the ovaries have overreacted to the treatment and that large cysts have formed in the ovaries. This side effect is common (may affect up to 1 out of 10 patients).
- Ovarian hyper stimulation syndrome may be severe when there is a significant enlargement of the ovaries, reduced urine production, weight gain, breathing difficulties or fluids in the abdomen or chest. This side effect is uncommon (may affect up to 1 out of 100 patients).

Additional side effects:

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

- Mild and short-lasting skin irritation at the injection site, such as: redness, itching or swelling.

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

- Nausea.
- Headache.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<http://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package, vial and syringe. The expiry date refers to the last day of that month.
- Store refrigerated at a temperature of 2°C-8°C.
- Store the packed tray inside the carton package to protect from light.
- Use the solution immediately after preparation.
- Do not use Cetrolimed if you notice a change in the appearance of the white powder in the vial. Do not use the preparation if you notice that the prepared solution is not clear and colorless or if it contains particles.
- Do not discard medicines in wastewater or domestic trash. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

What does the medicine contain?

The active ingredient is cetorelix. Each vial contains 0.25 mg cetorelix (as acetate).

In addition to the active ingredient the medicine also contains:

In the powder: mannitol.

In the solvent: sterile water for injection.

What does the medicine look like and what are the contents of the package?

Cetrolimed is a powder and solvent for solution for subcutaneous injection. The white powder comes in a glass vial with a rubber stopper and an aluminum gasket with a blue plastic cover on top of it. The solvent is a clear and colorless liquid in a prefilled syringe.

The vial of the powder contains 0.25 mg cetorelix (as acetate) and the prefilled syringe contains 1 ml solvent.

The product is supplied in a carton package that contains a packed tray containing:

One vial, one prefilled syringe and two needles as follows:

- One needle with a yellow mark for injecting the sterile water into the vial and for drawing the medicine that has formed out of the vial.
- One needle with a gray mark for injecting the medicine into the abdomen.

License holder and importer: Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak.

Manufacturer: Qilu Pharmaceutical Co., Ltd., Jinan, China.

This leaflet was revised in February 2025.

Registration number of the medicine in the national drug registry of the Ministry of Health:
178-39-38150

Instructions for dissolving and injecting Cetrolimed

- This section explains how to mix the powder and the sterile water (the solvent) together and then inject the medicine.
- Before starting to use this preparation, read these instructions for the first time in their entirety.
- This preparation is intended for you – do not allow anyone else to use it.
- Use each needle, vial and syringe only once.

Before you begin

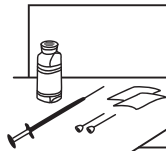
1. The product must be at room temperature prior to injecting it. Remove it from the refrigerator about 30 minutes before using it.

2. Wash your hands

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

3. Choose a clean surface and place everything you need on it:

- One vial of powder.
- A prefilled syringe with sterile water (solvent).
- One needle with a yellow mark – for injecting the sterile water into the vial and for drawing the medicine that has formed out of the vial.
- One needle with a gray mark – for injecting the medicine into your abdomen.
- Two alcohol swabs for disinfection (ask the pharmacist for a recommendation of alcohol swabs suitable for disinfection).



Mixing the powder with the water to prepare your medicine

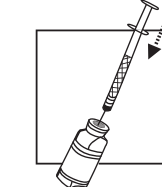
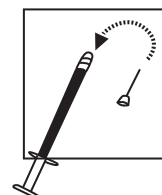
1. Remove the blue plastic cover of the vial

- Underneath, you will find a rubber stopper and an aluminum gasket – leave them in place.
- Clean the aluminum ring and the rubber stopper with an alcohol swab.



2. Adding the sterile water from the filled syringe into the vial with the powder

- Take the needle with the yellow mark out of its wrapping.
- Remove the cap from the syringe prefilled with solvent. Attach the yellow needle to the syringe and remove the cap of the needle.
- Hold the syringe and push the needle through the center of the rubber stopper into the vial.
- By slowly pushing the plunger of the syringe, inject the water in the syringe into the vial. Do not use any other source of water for this purpose.
- Leave the syringe stuck in the rubber stopper of the vial.



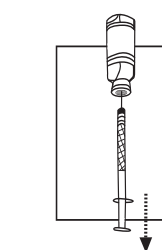
3. Mixing the powder and the water inside the vial

- Carefully hold the syringe and vial and gently mix the powder and water in the vial until you obtain a clear solution without particles.
- Avoid shaking, which will create bubbles.



4. Refilling the syringe with the medicine from the vial

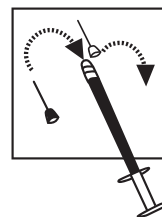
- Turn the vial upside down so that the rubber stopper is facing downward.
- Then, gently pull back the syringe plunger in order to draw the medicine from the vial into the syringe. Be sure not to pull the plunger completely out of the syringe. If you accidentally pull the plunger out of the syringe, this dose will no longer be sterile. Therefore, make sure to discard it and prepare a new dose (begin from step 1).
- If you have not drawn all of the solution and some solution is left in the vial, gently pull the needle out until the end of the tip of the needle is in the rubber stopper. You can follow the movement of the needle and the liquid by looking from the side through the gap in the rubber stopper.
- It is important to draw back into the syringe all of the solution from the vial.
- Put the cap back on the yellow needle. Unscrew the yellow needle from the syringe and lay the syringe aside.



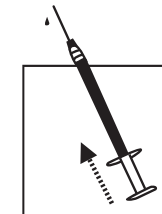
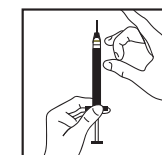
Preparing the injection site and injecting the medicine

1. Removing air bubbles

- Remove the injection needle with the gray mark from its wrapping and screw it onto the syringe. Remove the cap of the needle.

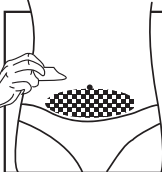


- Hold the syringe with the gray needle so that the needle points upward and check for air bubbles.
- To expel air bubbles, gently tap on the syringe with your finger until all the air collects at the top of the syringe – afterwards, gently push the plunger of the syringe until all air bubbles are expelled.
- Do not touch the gray needle and do not let the needle touch anything.



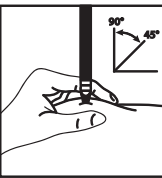
2. Disinfecting the injection site

- Choose an injection site in your abdomen area, preferably around the navel. To avoid local irritation of the skin, choose a different injection site in the abdomen each day.
- Clean the chosen injection site with the second alcohol swab – use a circular motion.



3. Insertion into the skin

- Hold the syringe in one hand – like you would hold a pencil.
- With the other hand, gently pinch up the skin around the injection site to form a fold.
- Gently insert the gray needle completely into the skin fold formed by pinching the skin at the injection site, at an angle of 45° to 90°, and then let go of the pinched skin.



4. Injecting the medicine

- Gently pull the plunger of the syringe back slightly. If blood appears in the syringe, stop and continue according to step 5.
- If no blood appears in the syringe, inject the solution **slowly** by pushing the plunger of the syringe all the way in.
- Once the entire content of the syringe is injected and the syringe is empty, slowly withdraw the needle from the skin at the same angle as it was inserted.
- Press gently on the injection site with the second alcohol swab.
- **If blood appears**
 - Withdraw the needle slowly at the same angle as it was inserted.
 - Press gently on the injection site with the second alcohol swab.
- Empty the content of the syringe into the sink and follow the instructions in step 6 below.
- Wash your hands and start again from step 1 with a new vial and syringe filled with solvent (a new Cetrolimed package).
- **Discarding the medicine**
 - The vial, syringe and needles are intended for single use only.
 - After use, put the caps back on the needles so they can be discarded safely.
 - Ask the pharmacist how to properly dispose of the used vial, syringe and needles.

