

CETROTIDE®

Cetrorelix acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CETROTIDE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CETROTIDE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CETROTIDE is used for

CETROTIDE is used to prevent too early or premature ovulation during a controlled ovarian stimulation as part of an assisted reproduction cycle (eg IVF, ICSI, GIFT).

CETROTIDE prevents the effects of a natural hormone called luteinising hormone releasing hormone (LHRH). LHRH controls the secretion of another hormone, called luteinising hormone (LH), which induces ovulation during the menstrual cycle. Ovulation that is too early is undesirable during hormone treatment for ovarian stimulation, because only mature egg cells are suitable for fertilisation. CETROTIDE is given to prevent premature ovulation.

Your doctor may have prescribed CETROTIDE for another reason.

Ask your doctor if you have any questions about why CETROTIDE has been prescribed for you.

CETROTIDE is not addictive.

This medicine is available only with a doctor's prescription.

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 to CETROTIDE may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin.

Do not use CETROTIDE if you have, or have had, any of the following medical conditions:

- moderate or severe liver disease
- moderate or severe kidney disease.

Do not use CETROTIDE if you have already reached menopause.

Do not use CETROTIDE if you are pregnant or suspect that you might be pregnant.

Do not breastfeed while taking CETROTIDE.

It is not known whether CETROTIDE passes into breast milk.

Do not use CETROTIDE after the expiry date printed on the label of the vial, pre-filled syringe and the carton.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not use CETROTIDE if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start using CETROTIDE, talk to your doctor or pharmacist.

If you have not told your doctor about any of the above, tell them before you start using CETROTIDE.

Before you use it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Although there have been no reports so far, there is a possibility

that some medicines and CETROTIDE may interfere with each other.

How to use CETROTIDE

CETROTIDE is given as an injection under the skin (subcutaneously). It is given in the abdomen, usually near your navel.

How much to use and how often to use it

CETROTIDE comes in two strengths, 250µg and 3mg. Your doctor will tell you which one to use.

CETROTIDE 250µg:
The contents of one vial is given once daily, at 24 hour intervals, either in the morning or in the evening. It is given over several days. Your doctor or nurse will advise you on which days you should use it.

CETROTIDE 3mg:
The contents of one vial are given as a single dose on one day during the cycle. Your doctor will advise you when to use it.

How to use CETROTIDE

Your first injection of CETROTIDE should be performed by your doctor or nurse. You should remain under their supervision for 30 minutes after this injection in case of allergic reaction.

You may self-administer any further CETROTIDE injections after you have been provided with appropriate instructions from your doctor or nurse, including the signs, symptoms and treatment of allergic reactions.

Please see the end of this leaflet for instructions on how to administer the dose.

If you forget to use it

CETROTIDE 250µg:
CETROTIDE 250µg should be administered at 24 hour intervals.

If you forget to administer CETROTIDE 250µg at the right time, administer it as soon as you remember on the same day.

If you forget to administer CETROTIDE 250µg on one day, contact your doctor immediately and ask for advice.

CETROTIDE 3mg:
If you forget to administer CETROTIDE 3mg, contact your doctor immediately and ask for advice.

If you use too much (Overdose)

Immediately contact your doctor or the Poisons Information Centre (In Australia telephone 131 126. In New Zealand telephone 0800 764 766) if you are concerned that you have given yourself too much CETROTIDE.

Overdosage of CETROTIDE may result in it working for longer in your body, but it is unlikely to be associated with severe unwanted effects.

While you are using CETROTIDE

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using CETROTIDE.

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

Things you must not do

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

Do not use CETROTIDE to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

- Nausea
- Vomiting
- Diarrhoea
- Stomach pain or discomfort

These may be signs of overstimulation of the ovaries, which can sometimes occur during controlled ovarian stimulation with gonadotropins (hormones promoting egg maturation).

- Breathing difficulties
- A rapidly-developing skin rash
- Itching, hives
- Fever
- Fainting

These may be signs of an allergic reaction to CETROTIDE.

Administer the injection in a different place on your skin each day.

This will help to reduce any irritation.

As far as it is known, CETROTIDE does not impair your ability to drive or to operate machinery.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are using CETROTIDE.

Like other medicines, CETROTIDE may have unwanted side effects.

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)

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

After using CETROTIDE

Storage

Keep the vial(s) in a refrigerator at 2- 8°C. Do not freeze.

Keep the vial in the outer carton to protect it from light.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave it in the car on hot days.

CETROTIDE does not contain a preservative.

Use the preparation immediately after the CETROTIDE powder has been dissolved in the water.

Each vial and syringe should be used only once. Use a new vial and syringe for each dose.

There should not be any liquid left left over after you have given yourself your dose.

If there is any left over, this should not be used.

Disposal

If your doctor or pharmacist tells you to stop using CETROTIDE or the pack has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

CETROTIDE is a powder for injection. CETROTIDE 250µg is available in packs of one or seven vials. CETROTIDE 3mg is available in a pack with one vial.

Also, for each vial the packs contain:

- One pre-filled syringe with solvent (water for injections) for dissolving the powder in the vial
- One injection needle with a yellow mark to be used for injecting the water into the vial and withdrawing the solution from the vial
- One injection needle with a grey mark to be used for injecting the solution
- Two alcohol swabs for cleaning purposes

Ingredients

Active ingredients:

- Cetrorelix acetate

Other ingredients

- mannitol

CETROTIDE does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Cetrotide is supplied in Australia by:
Merck Serono Australia Pty Ltd
3-4/25 Frenchs Forest Rd
Frenchs Forest NSW 2086

For enquiries call: 1800 633 463

Cetrotide is supplied in New Zealand by:
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland

Australian Registration Numbers:

CETROTIDE 250µg:
AUST R 74888

CETROTIDE 3mg:
AUST R 74889

This leaflet was prepared in May 2011

HOW TO USE CETROTIDE

CETROTIDE is for injection under the skin of the lower abdominal wall, preferably around the navel. To minimise local irritation, use a different injection site each day.

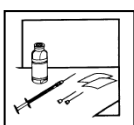
Dissolve CETROTIDE powder only with the water in the pre-filled syringe. Do not use a CETROTIDE solution if it contains particles or if it is not clear.

Before you administer CETROTIDE yourself, please read the following instructions carefully:

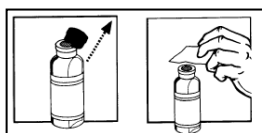
1. Wash your hands. It is important that your hands and all items you use are as clean as possible.



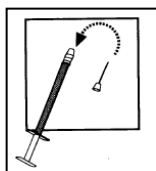
2. Lay out on a clean surface everything you need (one vial, one pre-filled syringe, one injection needle with a yellow mark, one injection needle with a grey mark and two alcohol swabs).



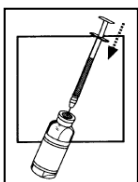
3. Flip off the plastic cover of the vial. Wipe the aluminium ring and the rubber stopper with an alcohol swab.



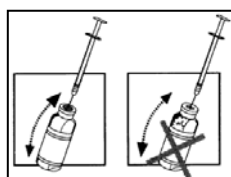
4. Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Put the needle on the syringe and remove the cover of the needle.



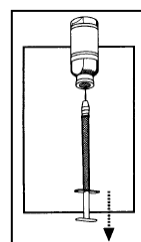
5. Push the needle through the centre of the rubber stopper of the vial. Inject the water into the vial by slowly pushing the plunger of the syringe.



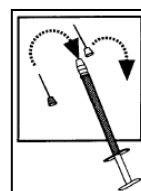
6. Leave the syringe on the vial. Gently agitate the vial until the solution is clear and without residue. Avoid forming bubbles during dissolution.



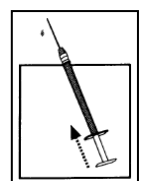
7. Draw the whole contents of the vial into the syringe. If solution is left in the vial, invert the vial, pull back the needle until the opening of the needle is just inside the stopper. If you look from the side through the gap in the stopper, you can control the movement of the needle and the liquid. It is important to withdraw the entire contents of the vial.



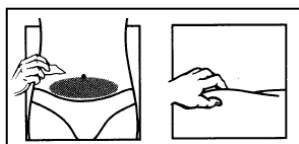
8. Detach the syringe from the needle and lay down the syringe. Take the injection needle with the grey mark and remove its wrapping. Put the needle on the syringe and remove the cover of the needle.



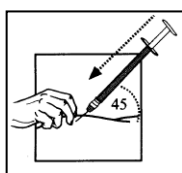
9. Invert the syringe and push the plunger until all air bubbles have been expelled. Do not touch the needle or allow the needle to touch any surface.



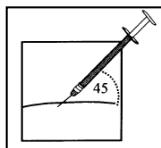
10. Choose an injection site in the area of the lower abdominal wall, preferably around the navel. Take the second alcohol swab and clean the skin at the injection site. Hold the syringe in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.



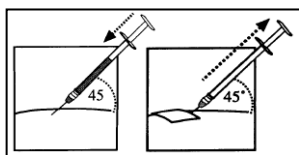
11. Hold the syringe as you would hold a pencil, insert the needle completely into the skin at an angle of about 45 degrees.



12. Once the needle has been inserted completely, release your grasp of the skin.



13. 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. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use as instructed by your nurse (put the covers on the needles to avoid injury).

There should not be any liquid left in the vial or the syringe after the dose has been given. However, if there is some left, this must not be used.