CETROTIDE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CETROTIDE?

CETROTIDE contains the active ingredient cetrorelix (as acetate). 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 fertilisation.

For more information, see Section 1. Why am I using CETROTIDE? in the full CMI.

2. What should I know before I use CETROTIDE?

Do not use if you have ever had an allergic reaction to CETROTIDE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use CETROTIDE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CETROTIDE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CETROTIDE?

- CETROTIDE is given as a subcutaneous (under the skin) injection in the lower abdomen.
- The contents of one vial of CETROTIDE are given once daily, at 24-hour intervals, either in the morning or in the evening. It is given over several days. Your doctor will tell you how much CETROTIDE to use and when to inject it.

More instructions can be found in Section 4. How do I use CETROTIDE? in the full CMI.

5. What should I know while using CETROTIDE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CETROTIDE. • Tell your doctor if you become pregnant while using CETROTIDE.
Things you should not do	• Do not stop using this medicine suddenly without telling your doctor. • Do not change the dose unless your doctor tells you to. • Do not give CETROTIDE to anyone else, even if they have the same condition as you.
Driving or using machines	• CETROTIDE is not expected to impair your ability to drive or to operate machinery.
Looking after your medicine	• Store CETROTIDE at 2°C to 8°C (Refrigerate. Do not freeze).

	• For patients: Should refrigeration be unavailable, CETROTIDE can be stored below 30°C for a single period of up to 3 months after which it must be discarded.

For more information, see Section 5. What should I know while using CETROTIDE? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor if you experience any side effects.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CETROTIDE®

Active ingredient: *cetrorelix (as acetate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CETROTIDE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CETROTIDE.**

Where to find information in this leaflet:

1. Why am I using CETROTIDE?
2. What should I know before I use CETROTIDE?
3. What if I am taking other medicines?
4. How do I use CETROTIDE?
5. What should I know while using CETROTIDE?
6. Are there any side effects?
7. Product details

1. Why am I using CETROTIDE?

CETROTIDE contains the active ingredient cetrorelix (as acetate).

CETROTIDE belongs to a group of medicines called "anti-gonadotropin-releasing hormones."

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 fertilisation (IVF).

2. What should I know before I use CETROTIDE?

Warnings

Do not use CETROTIDE if:

- you are allergic to cetrorelix (as acetate), or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.
- you have or have had moderate or severe liver or kidney disease
- you are pregnant or breastfeeding
- you have reached menopause.

Check with your doctor if you:

- take any medicines for any other condition
- have any other medical condition.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Talk to your doctor about any concerns you may have before undergoing treatment or before you start using CETROTIDE.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CETROTIDE.

4. How do I use CETROTIDE?

How much to use

- Treatment with CETROTIDE should be started under the supervision of a specialist doctor experienced in fertility treatment.
- CETROTIDE is given once daily, at 24-hour interval, 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.
- Follow the instructions provided and use CETROTIDE until your doctor tells you to stop.

When to use CETROTIDE

- Your doctor will tell you when to inject CETROTIDE.

How to inject CETROTIDE

- CETROTIDE is for injection under the skin of the lower abdominal wall. The injection site should be changed everyday to lessen possible injection site reactions.
- Your first injection of CETROTIDE should be given by your doctor or nurse. You should remain under their supervision after this injection in case of allergic reaction.
- After the first injection, you may administer CETROTIDE yourself.
- Do not attempt self-injection until you are sure of how to do it.

- Follow all instructions given to you by your doctor or nurse carefully. Follow these steps:

1. **Preparation**

- Wash your hands. It is important that your hands and all items you use are as clean as possible.
- Lay out everything you need on a clean surface (one vial of powder, one pre-filled syringe with sterile water, one needle with a yellow mark for injecting the sterile water into the vial and drawing the medicine from the vial, one needle with a grey mark for injecting the medicine and alcohol swabs (not provided in the pack)).
- Remove the flip-off cap from the vial and wipe the aluminium ring and the rubber stopper with an alcohol swab.

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

- Screw the needle with yellow mark onto the syringe. Carefully remove the needle cover.
- 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.
- With the needle still in the vial, gently swirl 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 solution.
- Do not use the dissolved solution if it contains particles or is not clear.

3. **Draw-up**

- Turn the vial upside down. Gently draw the whole contents of the vial into the syringe.
- It is important to withdraw the entire contents of the vial.
- Unscrew and discard the yellow needle into your sharps container.

4. **Injection**

- 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. Gently flick the syringe until all the air collects at the top and push the plunger until the air bubbles are gone.
- Do not touch the needle or allow the needle to touch any surface.
- Choose an injection site in the area of lower abdominal wall, preferably around the navel. Clean the skin at your chosen injection site with an alcohol swab if required.
- Hold the syringe with the grey needle in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.
- Slowly push the grey needle completely into your skin at an angle of about 45 to 90 degrees.
- Once the needle has been inserted completely, release your grasp of the skin.
- Slowly push down the plunger until all the solution has been injection. After all the solution is injected, withdraw the needle slowly.

- Gently press down the injection site with a cotton pad.
- Dispose of both the injection needle and the syringe in your sharps container. Do not re-use them.

Use a new vial and syringe for each use.

If you forget to use CETROTIDE

CETROTIDE should be used regularly at the same time each day. If you miss your dose at the usual time, contact your doctor or nurse immediately for advice.

If you use too much CETROTIDE

If you think that you have used too much CETROTIDE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CETROTIDE?

Things you should do

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

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.

Remind any doctor, dentist or pharmacist you visit that you are using CETROTIDE.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not change the dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

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

Looking after your medicine

- Store CETROTIDE at 2°C to 8°C (Refrigerate. Do not freeze).
- For patients: Should refrigeration be unavailable, CETROTIDE can be stored below 30°C for a single period of up to 3 months after which it must be discarded.
- Store in the original package in order to protect it from light.
- Inject the reconstituted CETROTIDE as soon as it is prepared. The final solution does not contain a preservative.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	**What to do**
• Headache • Nausea • Injection site reactions, such as redness, itching, swelling of the injection site • Signs of mild OHSS, such as abdominal pain or discomfort	**Speak to your doctor if you have any of these side effects and they worry you.**

Serious side effects

Serious side effects	**What to do**
Allergic reactions: • Swelling of the face, lips, tongue or other parts	**Call your doctor straight away, or go straight to the Emergency**

Serious side effects	What to do
of the body, shortness of breath, wheezing or difficulty breathing, skin rash, itching or hives • Signs of severe OHSS, such as lower abdominal pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced urine output and shortness of breath	**Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

In New Zealand, you can report side effects to Medsafe online at https://pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CETROTIDE contains

Active ingredient **(main ingredient)**	Cetrorelix (as acetate)
Other ingredients **(inactive ingredients)**	Mannitol

Do not take this medicine if you are allergic to any of these ingredients.

What CETROTIDE looks like

CETROTIDE is a sterile white powder in vial(s).

CETROTIDE is available in packs of one or seven vials.

Each pack contains:

- CETROTIDE 250 microgram powder in a glass vial
- Pre-filled syringe with solvent (water for injections) for dissolving the powder before injection
- Mixing needle with a yellow mark. It is to be used for injecting the solvent into the vial and withdrawing the solution from the vial

- Injection needle with a grey mark. It is used for injecting the solution

Australian Registration Number: AUST R 74888

Who distributes CETROTIDE

CETROTIDE is supplied in Australia by:

Merck Healthcare Pty Ltd

Suite 1, Level 1, Building B

11 Talavera Road

Macquarie Park NSW 2113

E-mail: medinfo.australia@merckgroup.com

Phone: 1800 633 463

CETROTIDE is supplied in New Zealand by:

Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Auckland

E-mail: medinfo.australia@merckgroup.com

Phone: 0800 426 252

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