CETROTIDE®

Cetrorelix (as 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 using CETROTIDE against the benefits it is expected to have for you.

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

Keep this information with your medicine.
You may need to read it again later.

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 fertilisation (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 fertilisation.

Ask your doctor if you have any questions about why CETROTIDE has been prescribed for you.
Your doctor may have prescribed it for another reason.

CETROTIDE is available only with a doctor's prescription.

CETROTIDE is not habit-forming.

Before you are given 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.

Do not use CETROTIDE if 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

Tell your doctor or pharmacist if:

- you have allergies to any foods, dyes, preservatives or any other medicines
- you are currently experiencing allergic symptoms.

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.

Compared to natural conceptions, the incidence of birth defects in women using assisted reproductive technologies (ART) may be slightly higher. It is unclear whether this is related to factors inherent to the couple's infertility or the ART procedures.

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.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while using CETROTIDE.

How CETROTIDE is given

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

Treatment with CETROTIDE should be started under the supervision of a specialist doctor experienced in fertility treatment.

CETROTIDE is given as a course of daily injections.

You should have your injection at the same time each day.

How much to inject

Your doctor will tell you how much CETROTIDE to use and when to inject it.

The contents of one vial of CETROTIDE 250 microgram are 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.

How to inject

CETROTIDE is given as a subcutaneous (under the skin) injection in the lower abdomen.

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 administer 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.

Where to inject

CETROTIDE is usually given in the lower abdomen. The injection site should be changed daily to minimise 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.

If you forget to inject 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 injected too much

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 or someone else has injected themselves with CETROTIDE.

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.

Things you must not do

Do not stop using CETROTIDE without telling your doctor.

Do not change the dose unless your doctor tells you to.
Changing your dose without advising your doctor can increase your risk of unwanted side effects or prevent the medicine from working properly.

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 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

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of an allergic reaction, including swelling of the face, lips, tongue, or other parts of the body; shortness of breath, wheezing or difficulty breathing; severe skin rash, itching or hives
- signs of severe OHSS such as lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amounts of urine and shortness of breath.

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)
- nausea, vomiting, diarrhoea, abdominal pain or discomfort.

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 patients.

After using CETROTIDE

Storage

Store 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.

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 store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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 vial(s). CETROTIDE is available in one presentation: 250 microgram in packs of one or seven vials.

Each pack contains:

- CETROTIDE 250 microgram powder in a glass vial
- Pre-filled syringe(s) with 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.

Ingredients

Active ingredient:

- Cetrorelix acetate

Inactive ingredient:

- Mannitol

Supplier

CETROTIDE is supplied in Australia by:

Merck Serono Australia Pty Ltd
3-4/25 Frenchs Forest Rd
Frenchs Forest NSW 2086
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
Email:
medinfo.australia@merckgroup.com
Phone: 0800 426 252

Australian Registration Numbers:

CETROTIDE 250 microgram:
AUST R 74888

This leaflet was prepared in April 2019.

A013-0419