

Package leaflet: Information for the user

Ceziboe 0.25 mg solution for injection in pre-filled syringe

cetrorelix (as acetate)

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

1. What Ceziboe is and what it is used for

What Ceziboe is

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

What Ceziboe is used for

Ceziboe 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 Ceziboe works

Ceziboe 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 Ceziboe 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 Ceziboe

Do NOT use Ceziboe

- if you are allergic to cetrorelix (as acetate) or to any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to medicines similar to Ceziboe (any other peptide hormones).

- if you are pregnant or breast-feeding
- if you have severe kidney disease.

Do not use Ceziboe 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 Ceziboe if you have an active allergy or have had allergies in the past.

Ovarian Hyperstimulation Syndrome (OHSS)

Ceziboe 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 Ovarian Hyperstimulation Syndrome (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 Ceziboe during more than one cycle

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

Liver disease

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

Kidney disease

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

Children and adolescents

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

Other medicines and Ceziboe

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

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

Driving and using machines

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

3. How to use Ceziboe

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 inject Ceziboe'.
- You start by using another medicine on day 1 of your treatment cycle. You then start using Ceziboe a few days later. (See next section 'How much to use').

How much to use

Inject the contents of one syringe (0.25 mg Ceziboe) 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 Ceziboe 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 Ceziboe

- 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 Ceziboe 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 Ovarian Hyperstimulation Syndrome (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA

Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ceziboe

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 syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

The unopened product may be stored in the original package at room temperature (not above 25°C) for up to three months.

Do not use it if the solution in the syringe is not clear and colourless or if it has particles in it.

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

6. Contents of the pack and other information

What Ceziboe contains

- The active substance is cetorelix (as acetate). Each pre-filled syringe (1 ml) contains 0.25 mg cetorelix (as acetate).
- The other ingredients are mannitol (E421), s-lactic acid and water for injection.

What Ceziboe looks like and contents of the pack

Ceziboe is a clear, colourless solution in a Type I clear glass barrel (1 ml) affixed with a 27 G ½ inch needle and stoppered with a bromobutyl elastomer plunger stopper. The pre-filled syringe has a white plunger rod and an automatic safety system.

It is available in a pack of 1 pre-filled syringe and in a multipack comprising 7 cartons, each containing 1 pre-filled syringe.

For each syringe, the pack contains:

- one pre-filled syringe assembled with a safety device containing the solution
- one alcohol swab for cleaning.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132JH Hoofddorp
The Netherlands

Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

S.C. Terapia S.A.
124 Fabricii Street
400632, Cluj-Napoca
Cluj County
Romania

Distributed by:

Ferring Ireland Ltd.
United Drug House
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names

Belgium	Ceziboe
Czech Republic	Ceziboe
Germany	Ceziboe
Greece	Ceziboe
France	Ceziboe
Hungary	Ceziboe
Ireland	Ceziboe
Italy	Ceziboe
The Netherlands	Ceziboe
Spain	Ceziboe
United Kingdom	Ceziboe

This leaflet was last revised in September 2021

HOW TO INJECT CEZIBOE

The different parts of Ceziboe pre-filled syringe are

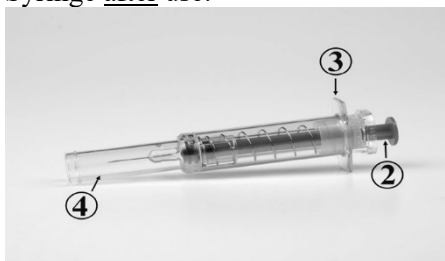
1. Rigid Needle Shield
2. Plunger
3. Finger-grip
4. Safety shield



Syringe before use:



Syringe after use:



This section tells you how to inject your medicine.

- Before starting to use this medicine, please first read these instructions, the whole way through.
- This medicine is only for you – do not let anyone else use it.
- Use each needle and syringe only once.

Before you start

1. This product 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 pre-filled syringe
 - one alcohol swab.

Preparing the injection site and injecting your medicine

1. Clean the injection site
 - Sit or lie down in a comfortable position. Choose an injection site on your belly. It is best around the belly button (navel) (Figure A). To reduce skin irritation, select a different part of your belly each day. Clean the injection area with an alcohol swab.
 - Remove the needle shield by pulling it straight off the syringe (Figure B). Discard the needle shield. **To prevent infection, do not touch the needle or let it come in contact with any surface before the injection.** A small air bubble in the syringe is normal. To be sure that you do not lose any medicine from the syringe, do not try to remove air bubbles from the syringe before giving the injection.



Figure A

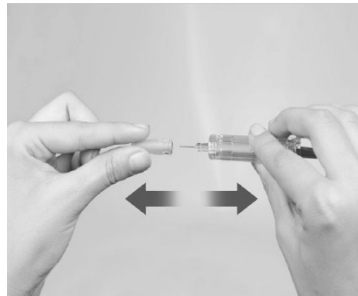


Figure B

2. Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger of one hand during the entire injection (Figure C).



Figure C

3. 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 needle completely into your skin at an angle of about 45 to 90 degrees – then let go of your skin.

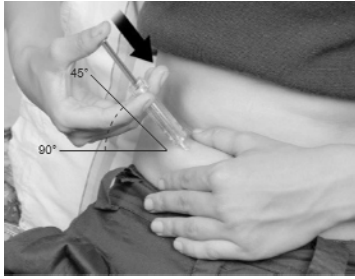


Figure D

4. 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. Inject all of the medicine in the syringe by **gently** pressing down on the plunger as far as it goes (Figure E). **Warning: Do not press down firmly, since this will activate the safety shield of the needle, see Step 6.** When the syringe is empty, take out the needle slowly at the same angle keeping your finger on the plunger. Use your alcohol swab to gently apply pressure where you have just injected.



Figure E

5. **If blood appears**
Take out the needle slowly at the same angle. Use your 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 pre-filled syringe (Figure F).

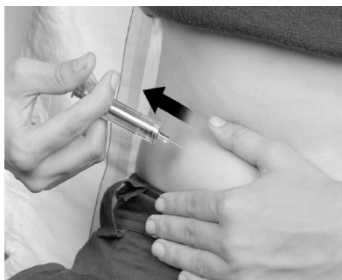


Figure F

6. Orient the needle away from you and others, and activate the safety shield by firmly pushing the plunger. The protective sleeve will automatically cover the needle and an audible "click" will be heard to confirm shield activation. (Figure G)



Figure G

Follow the instructions given to you by your nurse or doctor about the right way to throw away used syringes and needles. There may be national laws about the right way to dispose of used syringes, needles, and disposal containers.

NOTE:

- The safety system can only be activated once the syringe has been emptied.
- Activation of the safety system must be done only after removing the needle from the patient's skin.
- Do not replace the needle shield after injection.
- The safety system should not be sterilized.
- Activation of the safety system may cause minimal splatter of fluid. For optimal safety activate the system while orienting it downwards away from yourself and others.