

PACKAGE LEAFLET: INFORMATION FOR THE USER

Letrozole 2.5 mg film-coated tablets
(letrozole)

Read all of this leaflet carefully before you start taking 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 Letrozole tablets are and what they are used for
2. What you need to know before you take Letrozole tablets
3. How to take Letrozole tablets
4. Possible side effects
5. How to store Letrozole tablets
6. Contents of the pack and other information

1. WHAT LETROZOLE TABLETS ARE AND WHAT THEY ARE USED FOR

What Letrozole tablets are and how they work

Letrozole, the active ingredient in Letrozole tablets. It belongs to a group of medicines called aromatase inhibitors. It is a hormonal (or “endocrine”) breast cancer treatment. Growth of breast cancer is frequently stimulated by oestrogens which are female sex hormones. Letrozole reduces the amount of oestrogen by blocking an enzyme (“aromatase”) involved in the production of oestrogens and therefore may block the growth of breast cancer that needs oestrogens to grow. As a consequence tumour cells slow or stop growing and/or spreading to other parts of the body.

What Letrozole tablets are used for

Letrozole tablets are used to treat breast cancer in post-menopausal women. They can be used either before surgery to reduce the size of the tumour, or after surgery to help prevent the tumour from returning.

They can also be used in patients with advanced breast cancer to help stop the tumour spreading to other parts of the body.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LETROZOLE TABLETS

Follow all the doctor’s instructions carefully. They may differ from the general information in this leaflet.

Do not take Letrozole tablets

- If you are allergic to letrozole or any of the other ingredients of the medicine (listed in section 6),
- If you still have periods, i.e. if you have not yet gone through the menopause,
- if you are pregnant or if there is a possibility that you might be pregnant.
- if you are breast-feeding.

If any of these conditions apply to you, **do not take this medicine and talk to your doctor.**

Warnings and Precautions

Talk to your doctor or pharmacist before taking Letrozole tablets

- if you suffer from any serious kidney disease.
- If you have severe liver disease
- if you have a history of osteoporosis (thinning or wasting of bones) or bone fractures. (see also “Follow-up during letrozole treatment” in section 3).

If any of these conditions apply to you, **tell your doctor.** Your doctor will take this into account during your treatment with letrozole.

Your doctor may want to measure your bone density before and during your treatment. Drugs like Letrozole Tablets reduce the levels of female hormones. This can lead to a loss of minerals in bones and cause osteoporosis (decrease in bone density and strength).

Letrozole may cause inflammation in tendons or tendon injury (see section 4). At any sign of tendon pain or swelling – rest the painful area and contact your doctor.

Men

Letrozole is not to be used by men.

Children and adolescents (below 18 years)

Letrozole is not to be used by children or adolescents.

Older people (age 65 years and over)

Letrozole tablets can be used by people aged 65 years and over at the same dose as for other adults.

Other medicines and Letrozole tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Letrozole tablets and food and drink

Taking food and drink has no influence on your treatment with Letrozole tablets.

Pregnancy, breast-feeding and fertility

- You should only take Letrozole tablets when you have gone through the menopause. However, your doctor should discuss with you the use of effective contraception, as you may still have the potential to become pregnant during treatment with Letrozole tablets.
- You must not take Letrozole tablets if you are pregnant or breast feeding as it may harm your baby.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive or work with machinery if you feel dizzy, tired, drowsy or generally unwell when you start to take Letrozole Tablets.

Letrozole Tablets contain lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE LETROZOLE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet of letrozole to be taken once a day. Taking letrozole tablets at the same time each day will help you remember when to take your tablet. You will probably continue to take Letrozole tablets for a number of years.

The tablet can be taken with or without food and should be swallowed whole with a glass of water or another liquid.

Follow-up during Letrozole treatment

You should only take this medicine under strict medical supervision. Your doctor will regularly monitor your condition to check whether the treatment is having the right effect.

Letrozole may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may decide to measure your bone density (a way of monitoring for osteoporosis) before, during and after treatment.

If you take more Letrozole Tablets than you should

If you accidentally take too many Letrozole tablets than you have been told to take, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.

If you forget to take Letrozole Tablets

- If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to
- Otherwise, take the dose as soon as you remember, and then take the next tablet as you would normally
- Do not take a double dose to make up for the one that you missed.

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

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.

Most of the side effects are mild or moderate and will generally disappear after a few days to few weeks of treatment.

Some side effects, such as hot flushes, hair loss or vaginal bleeding, may be due to the lack of oestrogens in your body.

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LETROZOLE 2.5 mg
FILM-COATED TABLETS



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

Some side effects could be serious:

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

- Weakness, paralysis or loss of feeling in any part of the body (particularly arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (sign of a brain disorder, e.g. stroke).
- Sudden oppressive chest pain (sign of a heart disorder).
- Swelling and redness along a vein which is extremely tender and possibly painful when touched.
- Severe fever, chills or mouth ulcers due to infections (lack of white blood cells).
- Severe persistent blurred vision.
- Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones).

Rare (may affect up to 1 in 1,000 people):

- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm, leg or foot pain (signs that a blood clot may have formed).
- Rupture of a tendon (connective tissues that connect muscles to bones)

If any of the above occurs, tell your doctor straight away.

You should also inform the doctor straight away if you experience any of the following symptoms during treatment with letrozole:

- Swelling mainly of the face and throat (signs of allergic reaction).
- Yellow skin and eyes, nausea, loss of appetite, dark-coloured urine (signs of hepatitis).
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder).

Very common (may affect more than 1 in 10 people):

- Hot flushes
- Increased level of cholesterol (hypercholesterolaemia)
- Fatigue
- Increased sweating
- Pains in bones and joints (arthralgia)

If any of these affects you severely, tell your doctor.

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

- Loss of appetite or increased appetite
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhea
- Malaise (generally feeling unwell)
- Weight gain
- Raised blood pressure (hypertension)
- Abdominal pain
- Dry Skin
- Depression
- Headache
- Dizziness
- Hair loss
- Skin rash
- Muscle pain
- Bone problems (pain, bone thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also “Follow-up during letrozole treatment” in section 3)
- Swelling of arms, hands, feet, ankles (oedema) due to fluid retention
- Vaginal bleeding
- Palpitations, rapid heart rate
- Joint stiffness (arthritis)
- Chest pain.

If any of these affects you severely, tell your doctor.

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

- Urinary tract infections, urinating more often
- Breast pain
- Mental problems (anxiety, nervousness, irritability, loss of memory, drowsiness, somnolence)
- Sleep problems (sleepiness or difficulty in sleeping)
- Changes in sensation, including touch sensation (pins and needles), taste changes
- Eye problems such as cataract (loss of transparency of the lens of the eye), eye irritation, blurred vision, dry eyes
- Dry mouth or mouth ulcers
- Itchy skin or raised wheals
- Vaginal discharge, vaginal dryness
- Fever
- Thirst
- Weight loss
- Cough
- Pain or burning sensation in the hands or wrist (carpal tunnel syndrome).
- Increased level of enzymes
- Yellowing of the skin and eyes,
- High blood levels of bilirubin (a breakdown product of red blood cells)
- Dryness of mucous membranes

Not known: frequency cannot be estimated from the available data:

- Trigger finger, a condition in which your finger or thumb catches in a bent position.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LETROZOLE TABLETS

- Store in the original package.
- Keep this medicine out of the sight and reach of children.
- Do not take Letrozole tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- 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 Letrozole tablets contains

- The active substance is letrozole. Each film-coated tablets contains 2.5 mg letrozole.
- The other ingredients are lactose monohydrate, sodium starch glycollate, microcrystalline cellulose, hypromellose 6 cP, colloidal anhydrous silica, magnesium stearate.
- The film coat contains hypromellose 15 cP, macrogol 6000, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and tartrazine (E102).

What Letrozole tablets looks like and contents of the pack

Letrozole 2.5 mg film-coated tablets are yellow, circular, biconvex film-coated tablets plain on both sides.

Letrozole 2.5 mg film-coated tablets are available in blister packs of 14 and 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom

Manufacturer:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom

Cipla Europe NV, De Keyserlei 58-60 bus 19, Antwerpen, 2018, Belgium

This leaflet was last revised in 10/2021.

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Cipla

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Heading : 12pt
 Subheading : 10pt
 Body text: 9pt

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safety variation

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