

LETROZE® 2.5mg Tablets
(Letrozole)

1. What Letroze is and how it works?

Letroze contains an active substance called letrozole. 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 estrogens which are female sex hormones. Letroze reduces the amount of estrogen by blocking an enzyme (“aromatase”) involved in the production of estrogens and therefore may block the growth of breast cancer that needs estrogens to grow. As a consequence tumor cells slow or stop growing and/or spreading to other parts of the body.

2. What Letroze is used for?

Letroze is used to treat breast cancer in women who have gone through menopause i.e. cessation of periods. It is used to prevent cancer from happening again. It can be used as first treatment before breast cancer surgery in case immediate surgery is not suitable or it can be used as first treatment after breast cancer surgery or following five years treatment with tamoxifen. Letroze is also used to prevent breast tumor spreading to other parts of the body in patients with advanced breast cancer.

3. What you need to know before you take Letroze?

Follow all the doctor’s instructions carefully. They may differ from the general information in this leaflet. Do not take Letroze –

- If you are allergic to letrozole or to any of the other ingredients of this medicine.
- If you still have periods, i.e. if you have not yet gone through the menopause.
- If you are pregnant.
- If you are breast-feeding.

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

4. Warnings and precautions

Talk to your doctor before taking Letroze.

- If you have a severe kidney disease.
- If you have a severe liver disease.
- If you have a history of osteoporosis or bone fractures.

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

Children and adolescents (below 18 years)

Children and adolescents should not use this medicine.

Older people (age 65 years and over)

People aged 65 years and over can use this medicine at the same dose as for other adults.

Other medicines and Letroze

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

Pregnancy, breast-feeding and fertility

- You should only take Letroze 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 Letroze.
- You must not take Letroze if you are pregnant or breast feeding as it may harm your baby.

Driving and using machines

If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools or machines until you feel normal again.

Letroze contains lactose

Letroze contains lactose (milk sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

5. How to take Letroze?

Always take this medicine exactly as your doctor told you.

The usual dose is one tablet of Letroze to be taken once a day. Taking Letroze at the same time each day will help you remember when to take your tablet.

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

How long to take Letroze?

Continue taking Letroze every day for as long as your doctor tells you. You may need to take it for months or even years. If you have any questions about how long to keep taking Letroze, talk to your doctor.

Follow-up during Letroze 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. Letroze may cause thinning or wasting of your bones (osteoporosis) due to the reduction of estrogens 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 Letroze than you should

If you have taken too much Letroze, or if someone else accidentally takes your tablets, contact a doctor or hospital for advice immediately. Show them the pack of tablets. Medical treatment may be necessary.

If you forget to take Letroze

- 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.

If you stop taking Letroze

Do not stop taking Letroze unless your doctor tells you to.

6. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

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

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

Some side effects could be serious:

Rare or uncommon side effects (i.e. they may affect between 1 to 100 in every 10,000 patients):

- 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).
- 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).
- 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.

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-colored urine (signs of hepatitis).
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder).

Some side effects are very common. These side effects may affect more than 10 in every 100 patients.

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

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

Some side effects are common. These side effects may affect between 1 to 10 in every 100 patients.

- Skin rash
- Headache
- Dizziness
- Malaise (generally feeling unwell)
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhea
- Increase in or loss of appetite
- Pain in muscles
- Thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases
- Swelling of arms, hands, feet, ankles (edema)
- Depression
- Weight increase
- Hair loss
- Raised blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding

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

Other side effects are uncommon. These side effects may affect between 1 to 10 in every 1,000 patients.

- Nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia
- Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- Impairment of sensation, especially that of touch
- Eye disorders such as blurred vision, eye irritation
- Palpitations, rapid heart rate
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- Joint stiffness (arthritis)
- Breast pain
- Fever
- Thirst, taste disorder, dry mouth
- Dryness of mucous membranes
- Weight decrease
- Urinary tract infection, increased frequency of urination

- Cough
- Increased level of enzymes

Side effects with frequency not known.

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

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

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.

7. How to store Letroze?

- Keep out of the reach and sight of children.
- Do not use Letroze 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 store above 30°C.
- Store in the original package in order to protect from moisture.
- Do not use any pack that is damaged or shows signs of tampering.

8. Contents of the pack and other information

What Letroze contains:

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients are lactose monohydrate, cellulose microcrystalline, maize starch, sodium starch glycolate, magnesium stearate and silica colloidal anhydrous. The coating is composed of talc, macrogol, polyvinyl alcohol, titanium dioxide, quinolone talc Aluminium Lake, red iron oxide and black iron oxide.

What Letroze looks like and contents of the pack

- Letroze is supplied as film-coated tablets. The film-coated tablets are dark-yellow and round.
- Each blister pack contains 30 tablets.

Marketing Authorization Holder:



Manufacturer:



Importer:

