

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Letrozole Tablets is and what it is used for
2. What you need to know before you take Letrozole Tablets
3. How to take Letrozole Tablets
4. Possible side effects
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1. What Letrozole Tablets is and what it is used for

What Letrozole Tablets is and how it works

Letrozole Tablets 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 oestrogens which are female sex hormones. Letrozole Tablets 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 is used for

Letrozole Tablets 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. Letrozole Tablets is also used to prevent breast tumour spreading to other parts of the body in patients with advanced breast cancer.

If you have any questions about how Letrozole Tablets works or why this medicine has been prescribed for you, ask your doctor.

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 to any of the other ingredients of this 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,
- 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 have a severe kidney disease,
- if you have a severe liver disease,
- if you have a history of osteoporosis or bone fractures (see also “Follow-up during Letrozole Tablets 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 Tablets.

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.

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 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.

Pregnancy, breast-feeding and fertility

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.

- 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.

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.

Letrozole Tablets contains lactose

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

Letrozole Tablets contains 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. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet of Letrozole Tablets to be taken once a day. Taking Letrozole Tablets 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 Letrozole Tablets

Continue taking Letrozole Tablets 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 Letrozole Tablets, talk to your doctor.

Follow-up during Letrozole Tablets 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 Tablets 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 have taken too much Letrozole Tablets, 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 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 a forgotten tablet dose.

If you stop taking Letrozole Tablets

Do not stop taking Letrozole Tablets unless your doctor tells you to. See also the section above “How long to take Letrozole Tablets”.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 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 oestrogens 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:

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 Tablets:

- 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).

Some side effects are very common (may affect more than 1 in 10 people)

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

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

Some side effects are common (may affect up to 1 in 10 people).

- Skin rash
- Headache
- Dizziness
- Malaise (generally feeling unwell)
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea
- Increase in or loss of appetite
- Pain in muscles
- Thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also “Follow-up during Letrozole Tablets treatment” in section 3)
- Swelling of arms, hands, feet, ankles (oedema)
- Depression
- Weight increase
- Hair loss
- Raised blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding
- Palpitations, rapid heart rate
- Joint stiffness (arthritis)
- Chest pain

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

Other side effects are uncommon (may affect up to 1 in 100 people)

- 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
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- 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
- Yellowing of the skin and eyes
- High blood levels of bilirubin (a breakdown product of red blood cells)

Side effects with frequency 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.

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

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

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 Letrozole Tablets

- 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 carton after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage condition.
- Do not use any pack that is damaged or shows signs of tampering.

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 tablet contains 2.5mg Letrozole.

The other ingredients are:

Core Tablet: lactose monohydrate, maize starch, hypromellose (E464), sodium starch glycolate, cellulose microcrystalline (E460), colloidal anhydrous silica (E551), magnesium stearate (E572).

Film coating: hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), macrogol 400 & talc (E553b).

What Letrozole Tablets looks like and content of the pack:

Letrozole 2.5 mg Tablets are yellow, round, biconvex, film coated tablets plain on both sides. Letrozole Tablets are packed in blisters of 10 tablets, 14 tablets, 28 tablets, 30tablets, 50 tablets, 60 tablets, 84 tablets, 90 tablets, 98 tablets, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer:

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

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

Name of the member state	Name of the medicinal product
The Netherlands	Letrozol Accord 2.5 mg filmomhulde tabletten
Austria	Letrozol Accord 2.5 mg filmtabletten
Belgium	Letrozole Accord Healthcare 2.5 mg Filmtabletten / filmomhulde tabletten / comprimé pelliculé
Denmark	Letrozol Accord
Finland	Letrozol Accord 2,5 mg kalvopäällysteinen taabletti/ filmdragerad tablet
France	Létozole Accord Healthcare 2,5 mg comprimé pelliculé
Germany	Letrozol Accord 2.5 mg filmtabletten
Greece	Aromed 2,5 mg δισκία επικαλυμμένα με λεπτό υμένιο
Ireland	Letrozole 2.5 mg film-coated tablets
Italy	ZOLOBREST 2,5 mg Compresse rivestite con film
Norway	Letrozol Accord 2,5 mg filmdrasjerte tabletter
Portugal	Letrozol Accord
Spain	Letrozol Accord 2,5 mg comprimidos recubiertos con película EFG
Sweden	Letrozol Accord 2.5mg Filmdragerade tabletter

This leaflet was last revised in 10/2023