

PACKAGE LEAFLET: INFORMATION FOR THE USER
Letrozin 2.5 mg, film-coated tablets
letrozole

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Letrozin 2.5 mg is and what it is used for
2. Before you take Letrozin 2.5 mg
3. How to take Letrozin 2.5 mg
4. Possible side effects
5. How to store Letrozin 2.5 mg
6. Further information

1. What Letrozin 2.5 mg is and what it is used for

Letrozole 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. As a consequence tumour cells slow or stop the growing and/or spreading to other parts of the body.

Letrozole is used to prevent breast cancer happening again. It can be used as a first treatment after breast surgery or following five years of treatment with tamoxifen. Letrozole is also used to prevent breast tumour spreading to other parts of the body in patients with advanced disease.

Letrozole should only be used for

- oestrogen receptor-positive breast cancer and
- only in women after menopause i.e. cessation of periods.

2. Before you take Letrozin 2.5 mg

Do not take Letrozin 2.5 mg

- if you are **allergic (hypersensitive) to letrozole or to any of the other ingredients** of Letrozin 2.5 mg (see section 6, What Letrozin 2.5 mg contains).
- 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**.

Take special care with Letrozin 2.5 mg

- if you suffer from a disorder or disease which affects your **liver** or **kidneys**.
- if you have a **history of osteoporosis or bone fractures**. Letrozole may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may therefore decide to measure your bone density before, during and after treatment. Your doctor can give you medicine to prevent or treat the bone loss.

If any of these conditions apply to you, **contact your doctor before taking this medicine**.

Children and adolescents (below 18 years)

Children or adolescents should not use letrozole.

Older people (aged 65 years and over)

People aged 65 years and over can use letrozole at the same dose as for other adult.

Taking other medicines

Other medicines may be affected by letrozole. They, in turn, may affect how well letrozole works.

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Letrozin 2.5 mg with food and drink

Food and drink do not affect letrozole.

Pregnancy and breast-feeding

Letrozole **should not be used during pregnancy and breast-feeding** as it may harm your baby. Contact your doctor immediately if you think you are pregnant.

Letrozole is only used to treat breast cancer in post-menopausal women. However, if you recently became postmenopausal or if you are perimenopausal, your doctor should discuss with you about the necessity of a pregnancy test before taking letrozole and of contraception as you might have the potential to become pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Important information about some of the ingredients of Letrozin 2.5 mg

Letrozole tablets contain the milk sugar **lactose**. If you have been told by your doctor that

you have an **intolerance to some sugars**, such as lactose, contact your doctor before taking this medicinal product.

3. How to take Letrozin 2.5 mg

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

The tablet should be swallowed whole with a glass of water or another liquid.

The usual dose is **one tablet taken once daily**. No dosage adjustment is required for elderly patients or for patients with mild kidney problems.

If you take more Letrozin 2.5 mg than you should

If you have taken too much letrozole, or if someone else accidentally took your tablets, contact your doctor, pharmacy or hospital for advice immediately.

If you forget to take Letrozin 2.5 mg

Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time.

If you stop taking Letrozin 2.5 mg

Do not stop taking letrozole even if you are feeling well, unless your doctor tells you. Your doctor will advise you on how long you should continue to take your tablets. You may need to take it for months or even years.

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

4. Possible side effects

Like all medicines, letrozole 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.

Some Side effects could be serious.

These side effects are rare or uncommon, (i.e. occurring in at least 1 in 10,000, but in less than 1 in 100 treated patients.)

- if you experience weakness, paralysis or loss of feeling in an arm or leg or any other part of the body, loss of coordination, nausea, or difficulty in speaking or breathing (sign of a brain disorder, e.g. stroke).
- if you have sudden oppressive chest pain (sign of a heart disorder).
- if you experience difficulty in breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm or leg (foot) pain (signs that a blood clot may have formed).
- if you experience swelling and redness along a vein which is extremely tender and possibly painful when touched.

- if you get severe fever, chills or mouth ulcers due to infections (lack of white blood cells).
- if you get severe persistent blurred vision.

If you get any of listed above tell your doctor straight away.

Other side effects can be:

Very common (occurring in at least 1 in 10 treated patients)

- increased sweating
- pain in bones and joints (arthralgia)
- hot flushes, fatigue including weakness or loss of strength

Common (occurring in at least 1 in 100, but in less than 1 in 10 treated patients)

- increase in or loss of appetite, high level of cholesterol
- sad mood (depression)
- headache, dizziness
- nausea, vomiting, indigestion, constipation, diarrhoea
- hair loss and skin rash
- muscle pain, bone pain, thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also section 2, Before you take Letrozin 2.5 mg)

- weight increase
- generally feeling unwell (malaise), swelling of arms, hands, feet, ankles (peripheral oedema)

Uncommon (occurring in at least 1 in 1,000, but in less than 1 in 100 treated patients)

- urinary tract infection
- tumour pain
- reduction in the number of white blood cells
- swelling of body parts (general oedema)
- anxiety, nervousness, irritability
- drowsiness, insomnia, memory problems, impairment of sensation (especially that of touch), taste disorder, brain infarction (cerebrovascular accident)
- lens opacity (cataract), eye irritation, blurred vision
- palpitations, rapid heart rate
- inflammation of the wall of a vein, raised blood pressure, heart problems (ischemic cardiac events)
- shortness of breath, cough
- Abdominal pain, inflammation of the mucous lining of the mouth, dry mouth
- increased liver enzymes
- itching, dry skin, hives
- joint stiffness
- increased frequency of urination • vaginal bleeding, vaginal discharge or dryness, breast pain
- fever, dryness of mucous membranes, thirst
- weight loss

Rare (occurring in at least 1 in 10,000, but in less than 1 in 1,000 treated patients)

- blood clot in the lung artery (pulmonary embolism), blood clot in the artery (arterial thrombosis), stroke (cerebrovascular infarction)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use letrozole after the expiry date which is stated on the blister and carton after EXP. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Letrozin 2.5 mg contains

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients are lactose monohydrate, cellulose microcrystalline (E460), maize starch pregelatinised, sodium starch glycolate, magnesium stearate (E572), colloidal silicon dioxide (E551). The ingredients in the tablet coating are macrogol, talc (E553b), hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172).

What Letrozin 2.5 mg looks like and contents of the pack

Letrozole is a yellow film-coated round tablet, inscribed with L900 at one side and 2.5 on the other side.

Letrozole is available in blisters of 10, 28, 30, 50, 60, 84, 90, 98 or 100 tablets per box. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MA Holder

Meditrina Pharmaceuticals Ltd.
Irakleitou 117, 152 38, Chalandri, Greece
Tel: +30 210 6726260

Manufacturer

Synthon Hispania SL