

PACKAGE LEAFLET

Package leaflet: Information for the patient

Letrozole Mylan 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.

In this leaflet:

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

1. What Letrozole Mylan is and what it is used for

What Letrozole Mylan is and how it works

Letrozole Mylan Tablets contain 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 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 Mylan is used for

Letrozole is used to treat breast cancer in women who have gone through menopause i.e. cessation of periods.

It is used to help prevent the 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 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 works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Letrozole Mylan

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

Do not take Letrozole Mylan

- 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

- 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 your treatment with Letrozole Mylan” 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 Mylan.

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 Mylan

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 Letrozole when you have gone through the menopause. However, your doctor should discuss with you about using effective contraception, as you may still have the potential to become pregnant during treatment with Letrozole.
- You must not take Letrozole 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 Mylan contains lactose and sodium

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 medicine.

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

3. How to take Letrozole Mylan

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 Mylan to be taken once a day. Taking Letrozole Mylan 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 Mylan

Continue taking Letrozole Mylan 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 Mylan, talk to your doctor.

Follow-up during your treatment with Letrozole Mylan

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 Mylan 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 Mylan than you should

If you have taken too much Letrozole Mylan, 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 Mylan

- 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 Letrozole Mylan

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

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 in 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

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

- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm or leg or foot pain (signs that a blood clot may have formed)

Not known (frequency cannot be estimated from the available data)

- 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)

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

Other possible side effects

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

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

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

Common (may affect up to 1 in 10 people)

- Palpitations, rapid heart rate
- Chest pain
- Skin rash
- Joint stiffness (arthritis)
- Headache
- Dizziness
- Malaise (generally feeling unwell)
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea
- Increase in or loss of appetite
- Pain in muscles or bones
- Thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also "Follow-up during your treatment with Letrozole Mylan" 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

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

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
- Yellowing of the skin and eyes
- High levels of bilirubin (a breakdown product of red blood cells)
- 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
- Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)

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

- Rupture of a tendon (connective tissues that connect muscles to bones)

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 or pharmacist. 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 Mylan

Keep this medicine out of the sight and reach of children.

Do not use Letrozole Mylan after the expiry date, which is shown on the label or carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Letrozole Mylan contains

The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.

The other ingredients are lactose monohydrate (see section 2, 'Letrozole contains lactose and sodium'), microcrystalline cellulose, maize starch, colloidal anhydrous silica, sodium starch glycolate and magnesium stearate. The tablet coating contains iron oxides (E172), hypromellose, polydextrose, macrogol, triacetin, the colourant Quinoline yellow (E104) and titanium dioxide (E171).

What Letrozole Mylan looks like and contents of the pack

Your medicine comes as a dark yellow, capsule-shaped, film-coated tablet marked 'LZ 2.5' on one side and 'G' on the other.

Letrozole Mylan is available in blister packs or bottles of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 98, 100, 112, 120, 180, 200 and 500 tablets, and in perforated unit dose blisters of 30 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturers:

Delpharm Lille S.A.S., Parc d'activités Roubaix-Est, 22 rue de Toufflers – CS 50070, 59452 Lys Lez Lannoy, France

Mylan Hungary Kft, Mylan utca 1, Komárom, 2900, Hungary

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

Austria:	Letrozol Arcana
Cyprus:	Letrozole / Generics
Czech Republic:	Letmylan
Denmark:	Letrozol Mylan

France:	Letrozole Viatris
Greece:	Letrozole Mylan
Ireland:	Letrozole Mylan
Italy:	Letrozolo Mylan Generics
Netherlands:	Letrozole Mylan
Norway:	Letrozol Mylan
Portugal:	Letrozol Mylan
Spain:	Letrozol Viatris
Sweden:	Letrozol Mylan

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