

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## LETROLE

### *Letrozole Film-coated Tablets 2.5 mg*



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## What is in this leaflet

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This leaflet answers some common questions about Letrole tablets. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking Letrole against the benefits they expect it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

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## What Letrole is used for and how it works

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Letrole is used for the treatment of breast cancer in women who are post-menopausal, i.e. women who no longer have periods, either because of their natural age, or following surgery or chemotherapy.

Letrole contains the active ingredient, letrozole. It belongs to a family of medicines called aromatase inhibitors, also referred to as "anti-oestrogens" as they function by reducing the production of oestrogen in your body.

The growth of certain types of breast cancer is stimulated by oestrogen. These cancers are known as "oestrogen-dependent." Reducing the production of oestrogen may help to prevent the cancer from growing.

This may be the first time you are taking an "anti-oestrogen" such as Letrole or you may have taken another "anti-oestrogen" such as tamoxifen in the past.

Your doctor may, however have prescribed Letrole for another

reason. Ask your doctor if you have any questions about why Letrole has been prescribed for you.

There is no evidence that Letrole is addictive.

Letrole is available only with a doctor's prescription.

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## Before you take Letrole

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### *When you must not take it*

**Do not take Letrole if you are allergic to letrozole, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take Letrole if you are still having periods.**

This medicine is intended only to be used in women who are no longer having periods, i.e. have gone through menopause.

**Do not take Letrole if you are pregnant or breast feeding as it may harm your baby.**

**Do not take Letrole after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.**

If it has expired, or is damaged, return it to your pharmacist for disposal.

**Talk to your doctor or pharmacist if you are not sure whether you should take this medicine.**

### *Before you start to take it*

**Tell your doctor or pharmacist before taking Letrole if you have:**

- severe kidney disease
- severe liver disease
- a history of osteoporosis or bone fractures
- lactose intolerance.

Your doctor may want to take special precautions while you are taking this medicine.

While you should only take Letrole when you have gone through menopause, your doctor should discuss with you the use of effective contraception. You may still have the potential to become pregnant during treatment with Letrole.

**Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Letrole.**

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.** Other medicines may be affected by Letrole or they may affect how well it works.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking this medicine.

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## How to take Letrole

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**Follow the directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

## **How much to take**

The usual dose is one Letrole tablet taken daily.

## **How to take it**

Swallow the tablet with a glass of water or other liquid. Do not crush or chew it. If you get an upset stomach after taking the tablet, take it with a meal or after a snack.

## **When to take it**

Take your Letrole at about the same time each day.

Taking your medicine at about the same time each day will have the best effect. It will also help you remember when to take the tablets.

## **How long to take it for**

Continue taking Letrole for as long as your doctor or pharmacist tells you to. Your doctor will check your progress to make sure the medicine is working and will decide how long your treatment should continue.

**If you are unsure, talk to your doctor.**

## **If you forget to take it**

**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 go back to taking your medicine as you normally would.**

**Do not take a double dose to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

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# **While you are taking Letrole**

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## **Things you must do**

**Tell your doctor immediately if you become pregnant while taking Letrole.**

You should not take this medicine while you are pregnant.

**Follow your doctor's instructions carefully.**

If you do not follow your doctor's instructions, your treatment may not help or you may have unwanted side effects.

**Make sure you go to all of your doctor's appointments so that your progress can be checked.**

Your doctor may want you to have tests from time to time to check on your progress and detect any unwanted side effects.

**Tell any other doctor, dentist or pharmacist who treats you that you are taking Letrole.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Letrole.**

## **Things you must not do**

**Do not use Letrole to treat any other complaints unless your doctor tells you to.**

**Do not give Letrole to anyone else, even if their symptoms seem similar to yours.**

## **Things to be careful of**

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Letrole until you know how it affects you.**

This medicine may cause dizziness or tiredness in some people. If you think you have any of these symptoms, do not drive or do anything else that could be dangerous.

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# **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Letrole.** All medicines can have

some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

**Tell your doctor if you notice any of the following side effects and they worry you:**

- swelling of the feet, ankles or other parts of the body due to fluid build up
- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis
- vaginal spotting or bleeding
- whitish, thick vaginal discharge, vaginal dryness
- headache
- fever
- tiredness, sleepiness, weakness or dizziness
- difficulty sleeping
- numbness or tingling in hands or feet
- mood changes such as anxiety, nervousness, irritability and depression (sad mood)
- forgetfulness
- change in sense of taste
- blurred vision or eye irritation
- stomach upset, nausea (feeling sick) or vomiting, pain in the abdomen
- constipation
- diarrhoea
- dry mouth, sore mouth, mouth ulcers and cold sores
- increased thirst
- breast pain
- hot flushes
- increased sweating
- appetite or weight changes
- hair thinning
- urgent need to urinate (pass water)
- pain or burning sensation when urinating, which may be a sign of an infection
- fast or irregular heartbeats
- thinning of bones (osteoporosis), leading to bone fractures in some cases
- locking of the finger and pain (trigger finger).

**Tell your doctor immediately or go to the Emergency department at your nearest hospital if you notice any of the following:**

- signs that blood clots may have formed, such as sudden severe headache, sudden loss of co-ordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing.
- constant "flu-like" symptoms (chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy) that could be a sign of blood problems.
- tightness or feeling of heaviness in the chest or pain radiating from your chest to your arms or shoulders, neck, teeth or jaw, abdomen or back (sign of angina pectoris or heart attack)
- numbness or weakness in arm or leg or any part of the body, loss of coordination vision changes, sudden headache, nausea, difficulty speaking or breathing (sign of stroke).
- 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)

The above list includes serious side effects. You may require urgent medical attention or hospitalisation.

**Tell your doctor if you notice anything else that is making you unwell.**

Other side effects not listed above may happen in some people.

Some of these side effects can only be found by laboratory testing.

Ask your doctor or pharmacist to answer any questions you may have.

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## In case of overdose

You must only take the number of tablets that you have been told.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your**

**nearest hospital, if you think that you may have taken too much, or if anyone else has taken any Letrole by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

Keep telephone numbers for these places handy.

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## After taking Letrole

### Storage

Keep your Letrole in the pack until it is time to take them.

Keep your Letrole in a cool dry place where the temperature stays below 25°C.

Do not store Letrole or any other medicine in the bathroom or near a sink. Do not leave the tablets in the car or on window sills. Heat and dampness can destroy some medicines.

Keep Letrole where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

Do not use the medicine after the expiry date printed on the pack.

If your doctor tells you to stop taking this medicine, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## Product description

### What it looks like

Letrole 2.5 mg tablets are dark yellow, capsule shaped, film-coated, slightly biconvex tablets, debossed with "LZ 2.5" on one side and "G" on the other.

The tablets are packed in blister packs containing 30 tablets.

## Ingredients

Each Letrole tablet contains 2.5 mg of the active ingredient letrozole.

The tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- magnesium stearate
- colloidal silicon dioxide.

The film coating contains:

- hypromellose
- polydextrose
- triacetin
- macrogol
- iron oxide yellow (E172)
- quinoline yellow aluminium lake (E104),
- iron oxide red (E172)
- titanium dioxide.

Letrole does not contain sucrose, gluten or tartrazine.

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## If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

### Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### Date of Information

26 June 2019  
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