

NEW ZEALAND CONSUMER MEDICINE INFORMATION

LETROLE

Letrozole Film-coated Tablets 2.5 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Letrole.

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.

What Letrole is taken for

Letrole is taken 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 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.

This medicine is available only with a doctor's prescription.

Before you take Letrole

When you must not take it

Do not take Letrole if you have an allergy to:

- any medicine containing letrozole
- any of the ingredients listed at the end of this leaflet.

Some of the 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 this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast feed if you are taking this medicine.

There is a possibility that 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- 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.

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Letrole.

Other medicines may be affected by Letrole or they may affect how well it works.

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

How to take Letrole

Follow all 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 medicine at about the same time each day.

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

How long to take it

Continue taking your medicine for as long as your doctor tells you.

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 that you missed.

This may increase the chance of you getting an unwanted side effect.

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.

While you are taking Letrole

Things you must do

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

Tell any other doctors, dentists or pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep 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.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Letrole 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.

In case of overdose

If you take too much (overdose)

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else has taken too much Letrole. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Letrole.

This medicine helps most people with breast cancer, but it may have unwanted side effects in a few people.

All medicines can have side 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.

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.

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

Active Ingredient:

Letrole contains 2.5 mg of Letrozole as the active ingredient..

Inactive Ingredients:

Letrole also contains:

- 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.

Contains lactose and sulfites.

If you want to know more

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

Who supplies this medicine

Letrole is supplied in New Zealand by:

Viatris Ltd,
PO Box 11-183,
Ellerslie,
Auckland
www.viatris.co.nz
Telephone: 0800 168 169

Date of Preparation

04 May 2023
(Based on datasheet dated 04 May 2023)