

LETARA

Letrozole

2.5 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking LETARA.

This leaflet answers some common questions about LETARA. It does not contain all the available information. 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 LETARA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What LETARA is used for

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

LETARA contains that active ingredient, 2.5 mg of letrozole and is presented in tablets.

Letrozole is an aromatase inhibitor – this family of medicines, which can be referred, also as “anti-oestrogens”, function by decreasing the production of oestrogen in your body.

The growth of certain types of breast cancer is promoted by oestrogen. These cancers are known as “oestrogen dependent”. Decreasing the production of oestrogen may aid to prevent the cancer from growing.

This may be the first time you are taking an “anti-oestrogen” such as LETARA or you might have taken another “anti-oestrogen” such as tamoxifen in the past.

Your doctor may have prescribed LETARA for another reason.

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

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

LETARA is also not addictive.

Before you take LETARA

When you must not take it

Do not take LETARA if you have an allergy to:

- any medicine containing letrozole or a class of medicines called aromatase inhibitors
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not take LETARA if you have not yet experienced menopause.

This medicine is intended only to be used in post-menopausal women i.e. women who no longer have periods.

Do not take this medicine if you are pregnant.

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

Do not breastfeed if you are taking this medicine.

Do not give this medicine to anyone else.

Do not use it to treat any other complaints unless your doctor says it is safe.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well, or worse, it might have an entirely unexpected effect

Do not take it if the packaging is torn or shows signs of tampering.

In such case, please return it to your pharmacist.

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

Before you start to use it

Tell your doctor if:

- 1. you have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 2. you have, or have had, the following medical conditions:**
 - severe liver disease
 - severe kidney disease
 - a history of osteoporosis or bone fractures
 - lactose intolerance.
- 3. you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.
- 4. you are breastfeeding or planning to breastfeed.**

Your doctor can discuss with you the risks and benefits involved.

While you should only take LETARA 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 LETARA.

If you have not told your doctor about any of the above, tell them before you start taking LETARA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your 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 LETARA.

Some medicines may interfere with LETARA.

These medicines may be affected by LETARA or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

How to take LETARA

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

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

The standard dose is one LETARA tablet taken per day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you take the wrong dose, LETARA may not work as well and your problem may not improve.

How to take it

LETARA tablets should be swallowed whole 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 LETARA at about the same time each day. Taking your tablets at 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

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

Your progress will be checked by your doctor to ensure this medicine is working. Your doctor will make a decision on how long your treatment should continue.

Tell your doctor if you are unsure.

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 unwanted side effects.

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

Ask your doctor or pharmacist for more hints if you have trouble remembering to take LETARA.

While you are taking LETARA

Things you must do

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

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

Tell your doctor immediately if you become pregnant while taking LETARA. This medicine should not be taken while you are pregnant.

Your doctor's instructions should be followed carefully. If you do not, your treatment may not be helpful or you may have unwanted side effects.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests from time to time to make sure the medicine is working and to pick up any unwanted side effects.

Things you must not do

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

Do not use LETARA to treat any other complaints unless your doctor says it is safe.

Things to be careful of

Be careful driving or operating machinery until you know how LETARA affects you. It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much LETARA.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Please keep these telephone numbers handy.

Side effects

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

LETARA helps most people, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- swelling of the feet, ankles or other parts of the body due to a build-up of fluid
- 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 change such as anxiety, nervousness, irritability and depression (sad mood)
- forgetfulness
- change in sense of taste
- blurred vision or eye irritation
- upset stomach, nausea (feeling sick) or vomiting, abdomen pain
- 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
- high levels of cholesterol in the blood (hypercholesterolaemia)
- abnormal liver function test results (blood test disorder)
- disturbed physical sensitivity (dysaesthesia)
- tendonitis, tenosynovitis and tendon rupture
- locking of the finger and pain (trigger finger).

If any of the following happen, stop taking LETARA and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- signs that blood clots could have formed, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the thighs or calves, chest pain, difficulty in breathing, coughing
- continuous “flu-like” symptoms such as chills, fever, sore throat, sores in mouth,

swollen glands, tiredness or lack of energy, which could be signs 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 heart attack or angina pectoris)
- numbness or weakness in arm or leg or any part of the body, loss of coordination, vision changes, sudden headache, nausea, difficulty in 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)

These may be serious side effects of LETARA. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

Some of these can be found only through laboratory testing.

After taking LETARA

Storage

Keep your LETARA tablets in the blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 30°C.

Do not store LETARA in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it 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 they have passed their expiry date, ask your pharmacist what to do with any unused medicine.
Return any unused medicine to your pharmacist.

Product description

What it looks like

LETARA 2.5 mg tablets are yellow to dark yellow, round, film coated, biconvex tablet, engraved with "L" on one face and plain on the other.

Ingredients

Each LETARA tablet contains 2.5 mg of Letrozole as the active ingredient.

Inactive ingredients:

- colloidal anhydrous silica
- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- maize starch
- sodium starch glycollate
- hydroxypropyl methylcellulose
- polyethylene glycol 8000
- talc
- titanium dioxide (E171)
- iron oxide yellow (E172)

Sponsor details

LETARA is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

This leaflet was revised on 19 February 2024
(based on data sheet dated 19 February 2024)