

Pharmacor Letrozole 2.5

Letrozole Tablets 2.5 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pharmacor Letrozole 2.5. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Pharmacor Letrozole 2.5 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 Pharmacor Letrozole 2.5 are used for

Pharmacor Letrozole 2.5 are used to treat breast cancer in women who are post-menopausal - that is, women who no longer have periods, either naturally due to their age or after surgery or chemotherapy.

Pharmacor Letrozole 2.5 are available in tablets containing 2.5 mg of the active ingredient, letrozole.

Letrozole belongs to a family of medicines called aromatase inhibitors. They are also called "antioestrogens" because they act by reducing the production of oestrogen in your body.

Oestrogen stimulates the growth of certain types of breast cancer. These cancers are called "oestrogen-dependent." Reducing the production of oestrogen may help to keep the cancer from growing.

This may be the first time you are taking an "antioestrogen" such as Pharmacor Letrozole or you may have taken another "antioestrogen" such as tamoxifen in the past.

Ask your doctor if you have any questions about why Pharmacor Letrozole 2.5 has been prescribed for you.

Your doctor may have prescribed Pharmacor Letrozole 2.5 for another reason.

Pharmacor Letrozole 2.5 are only available with a doctor's prescription. It is not addictive.

Before you take Pharmacor Letrozole 2.5

When you must not use it

Do not take Pharmacor Letrozole 2.5 if you have an allergy to:

- letrozole, the active ingredient in Pharmacor Letrozole
 - any other ingredients of Pharmacor Letrozole 2.5 listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing.

Do not take Pharmacor Letrozole 2.5 if you are still having periods.

This medicine is only used in women who are no longer having periods.

Women of child-bearing age who recently became postmenopausal or perimenopausal should use a proven method of birth control to avoid pregnancy, until your postmenopausal status is fully established.

Do not take Pharmacor Letrozole 2.5 if you are pregnant or breast feeding.

It may affect your baby if you take it while you are pregnant or breast feeding.

Do not take Pharmacor Letrozole 2.5 after the use by (expiry) date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work or it may make you feel unwell.

Do not take Pharmacor Letrozole 2.5 if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have severe kidney or liver disease.

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

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

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell them before you take Pharmacor Letrozole 2.5.

Taking other medicines

Tell your doctor 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 Pharmacor Letrozole 2.5 or they may affect how well it works.

Your doctor or pharmacist can tell you what to do when taking Pharmacor Letrozole 2.5 with other medicines.

How to take Pharmacor Letrozole 2.5

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

These directions 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 Pharmacor Letrozole 2.5 Tablet daily.

How to take it

Swallow the tablet with a glass of water or other liquid.

If your stomach is upset after taking the tablet, take it with a meal or after a snack.

How long to take it

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 tablet as you would normally.

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

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

If you take too much

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Pharmacor Letrozole 2.5. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Pharmacor Letrozole 2.5

Things you must do

If you become pregnant while taking Pharmacor Letrozole 2.5, tell your doctor immediately.

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.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want you to have blood tests from time to time to check on your progress and detect any unwanted side effects. Your doctor may also decide to monitor your bone health as this medicine may cause thinning or wasting of your bones (osteoporosis).

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Pharmacor Letrozole 2.5.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Pharmacor Letrozole 2.5.

Things you must not do

Do not use Pharmacor Letrozole 2.5 to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else, even if their symptoms seem to be 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 Pharmacor Letrozole 2.5 until you know how it affects you.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pharmacor Letrozole 2.5.

It may have unwanted side effects in some people in addition to its beneficial effects. All medicines 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 side effects. You may not experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency 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 coordination, 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 blood.
- 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.

The above side effects may be serious. You may need urgent medical attention or hospitalisation.

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), bone fractures

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 can only be found by laboratory testing.

After taking Pharmacor Letrozole 2.5

Storage

- Keep your tablets in the container until it is time to take them.
- Store the tablets below 25°C. Protect from moisture.
- Do not store Pharmacor Letrozole 2.5 in the bathroom or any other place that is hot or steamy.
- Do not leave the tablets in the car or on window sills.
Heat and dampness can destroy some medicines. Pharmacor Letrozole 2.5 will keep well if it is cool and dry.

Keep this medicine 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

If your doctor tells you to stop taking Pharmacor Letrozole 2.5 or the tablets have passed their use by (expiry date), ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Pharmacor Letrozole 2.5 are yellow, round, biconvex, film-coated tablets plain on both sides, supplied in blister pack and each pack contains 30 tablets.

Ingredients

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

The tablets also contain:

- Lactose
- Starch - maize
- Hypromellose
- Cellulose - microcrystalline
- Sodium starch glycollate (Type A)
- Silica - colloidal anhydrous
- Magnesium stearate
- Opadry 03B82927 yellow (Hypromellose, Titanium dioxide, Iron oxide yellow CI 77492, Macroglol 400 & Talc - purified)

Pharmacor Letrozole 2.5 does not contain sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of the Sponsor

Pharmacor Limited

Unit 5/36,
Campbell Avenue,
Cromer NSW 2099
Australia

AUST R 159589

TGA Approval: 3/06/2010

Date of Most Recent Amendment: 16 August 2010