

PHARMACOR LETROZOLE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PHARMACOR LETROZOLE?

PHARMACOR LETROZOLE contains the active ingredient letrozole. PHARMACOR LETROZOLE is used to treat breast cancer in post-menopausal women.

For more information, see Section [1. Why am I using PHARMACOR LETROZOLE ?](#) in the full CMI.

2. What should I know before I use PHARMACOR LETROZOLE?

Do not use if you have ever had an allergic reaction to letrozole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Your doctor will want to check your hormone levels to ensure you are no longer having periods. Your doctor may also send you for tests to check on your heart, liver, kidneys, and bones.

For more information, see Section [2. What should I know before I use PHARMACOR LETROZOLE ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PHARMACOR LETROZOLE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PHARMACOR LETROZOLE?

- The initial dose is (1) PHARMACOR LETROZOLE tablet a day, ideally at the same time each day to help you remember to take it
- Swallow your tablet with a glass of water or other liquid

More instructions can be found in Section [4. How do I use PHARMACOR LETROZOLE ?](#) in the full CMI.

5. What should I know while using PHARMACOR LETROZOLE?

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|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are taking PHARMACOR LETROZOLE. Keep all your doctor's appointments so that your progress can be checked.• Promptly get all blood tests, bone tests and any other tests on your liver, heart or kidneys done. Use effective contraception (birth control) to avoid becoming pregnant. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking this medicine suddenly• Do not give this medicine to someone else |
| Driving or using machines | <ul style="list-style-type: none">• PHARMACOR LETROZOLE may make you feel tired or dizzy and may impair your driving. |
| Drinking alcohol | <ul style="list-style-type: none">• PHARMACOR LETROZOLE may make you feel tired or dizzy. Alcohol may increase this effect |
| Looking after your medicine | <ul style="list-style-type: none">• Store it in a cool dry place below 25°C (room temperature) away from moisture, heat, or sunlight. |

For more information, see Section [5. What should I know while using PHARMACOR LETROZOLE?](#) in the full CMI.

6. Are there any side effects?

More common side effects include muscle/joints/back/breast pain, raised blood pressure/cholesterol, feeling tired, sick, annoyed, anxious, nervous, dizzy; headache, vertigo, hot flush, vomiting, cough, tummy pain, diarrhoea, frequent wee, constipation, sweating, hair loss, weight change, vaginal bleeding/discharge. More serious side effects include allergic reaction i.e. wheezing, difficulty breathing, swelling of lips, tongue/face, blisters/spreading rash on eyes, lips, face; yellow eyes/skin, unable to wee; loss of vision, balance, co-ordination; difficulty speaking, confusion, constant flu-like symptoms i.e. fever, chills, sore throat; bluish/pale skin, heart palpitations, irregular/fast heartbeat, crushing chest pain, numb/tingling limbs, bone fracture, tendonitis, pain or swelling around joints, tendon tears.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PHARMACOR LETROZOLE

Active ingredient(s): *letrozole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PHARMACOR LETROZOLE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PHARMACOR LETROZOLE .**

Where to find information in this leaflet:

- [1. Why am I using PHARMACOR LETROZOLE?](#)
- [2. What should I know before I use PHARMACOR LETROZOLE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PHARMACOR LETROZOLE?](#)
- [5. What should I know while using PHARMACOR LETROZOLE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PHARMACOR LETROZOLE?

PHARMACOR LETROZOLE contains the active ingredient **letrozole**. PHARMACOR LETROZOLE belongs to a class of medicines called 'aromatase inhibitors'. It is also commonly referred to as an "antioestrogen."

PHARMACOR LETROZOLE is used to treat breast cancer in women who no longer have a period (post-menopause) because of natural aging, surgery or by some other means. PHARMACOR LETROZOLE reduces the amount of a hormone (chemical) known as 'oestrogen' that your body produces naturally to reduce the spread of cancer.

2. What should I know before I use PHARMACOR LETROZOLE?

Warnings

Do not use PHARMACOR LETROZOLE if:

- you are allergic to letrozole, or any of the ingredients listed at the end of this leaflet.
- you are still having your period (pre-menopause).
- you are pregnant or are breast-feeding.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have a liver condition.

- have a problem with your kidneys.
- have a history of bone fractures or brittle bones from reduced bone mass ('osteoporosis').
- are allergic to any other medicines, dyes, or preservatives.
- During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Screening

PHARMACOR LETROZOLE can only be taken in women who are no longer having periods.

Your doctor may send you for a blood test to check your hormone levels and confirm this.

Monitoring during treatment

Your doctor may want to check on your bones during treatment using a bone density test or may send you for an X-ray.

Your doctor may also send you for blood tests from time to time to check how your heart, liver and kidneys are doing while taking PHARMACOR LETROZOLE, especially if you have a known condition affecting these. Your doctor may alter your treatment plan or ask you to stop taking it depending on the results.

Birth control

If you have recently entered menopause or are in the early stages of menopause, your doctor will discuss contraception options with you if you are able to become pregnant. You should not become pregnant while taking PHARMACOR LETROZOLE as it might harm your unborn baby.

Male patients

PHARMACOR LETROZOLE may reduce fertility in men.

Pregnancy and breastfeeding

Tell your doctor straight away if you are pregnant or intend to become pregnant. There are reports of abnormalities in babies born to mothers who took PHARMACOR LETROZOLE during pregnancy.

You must not take PHARMACOR LETROZOLE if you are breastfeeding or intend to breastfeed. It may pass into your breast milk and harm your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with PHARMACOR LETROZOLE and affect how it works. They include:

Medicines that may affect PHARMACOR LETROZOLE include:

- Anti-fungal medicines such as ketoconazole, itraconazole, voriconazole
- Medicines for HIV such as ritonavir
- Antibiotics such as clarithromycin, and telithromycin
- Methoxsalen used for some skin conditions
- Medicines for seizures (fits) such as phenytoin or phenobarbital
- Clopidogrel which you may be taking if you have had previously had a heart attack or a stroke
- Some antibiotics like rifampicin.
- Some other breast cancer medicines such as carbamazepine or tamoxifen.
- St. John's wort (a herbal extract) used in a variety of conditions.
- Other medicines that contain oestrogen or affect the amount of oestrogen in your body.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PHARMACOR LETROZOLE .

Your doctor may consider your treatment carefully if you are taking any of these medicines.

4. How do I use PHARMACOR LETROZOLE?

How much to take

- The usual dose is one (1) PHARMACOR LETROZOLE tablet a day.
- Follow the instructions provided by your doctor and take PHARMACOR LETROZOLE until your doctor tells you to stop.

How to take PHARMACOR LETROZOLE

- Swallow the tablet whole with a glass or water or other liquid.
- If your tummy is upset after you take the tablet you can take PHARMACOR LETROZOLE with a meal or after a snack

When to take PHARMACOR LETROZOLE

- PHARMACOR LETROZOLE should be used regularly at the same time each day to help you remember to take it.

How long to take PHARMACOR LETROZOLE

- Take PHARMACOR LETROZOLE for as long as your doctor tells you to.

If you forget to take PHARMACOR LETROZOLE

If you miss your dose at the usual time and it is almost time for your next tablet (in the next 2-3 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take your tablet as soon as you remember and then go back to taking the tablet as you normally would.

Do not take two tablets to make up for the dose you missed.

If you take too much PHARMACOR LETROZOLE

If you think that you have used too much PHARMACOR LETROZOLE , you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PHARMACOR LETROZOLE?

Things you should do

- Remind any doctor, dentist, or pharmacist you visit that you are taking PHARMACOR LETROZOLE .
- Keep all your doctor's appointments so that your progress can be checked.
- Promptly get all blood tests, bone tests and any other tests on your liver, heart or kidneys done so that your doctor can check these.
- Use birth control to avoid becoming pregnant.

Call your doctor straight away if you:

- Become pregnant or think you may be pregnant.
- Are experiencing an allergic reaction to the medicine.

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 trouble breathing.

Things you should not do

- Do not stop taking this medicine suddenly.
- Do not give PHARMACOR LETROZOLE to someone else.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PHARMACOR LETROZOLE affects you.

PHARMACOR LETROZOLE can make you feel tired or dizzy. You must not drive or operate machinery if you are experiencing this.

Looking after your medicine

Keep PHARMACOR LETROZOLE tablets inside the original packaging until it is time to take them.

Store it in a cool dry place below 25°C away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

You must only discard your medicine if your doctor has told you to stop taking it or the expiry date on the packaging has passed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Tummy problems:</p> <ul style="list-style-type: none"> • Constipation or diarrhoea • Indigestion or discomfort/pain • Throwing up (vomiting) <p>Vaginal problems:</p> <ul style="list-style-type: none"> • Spotting or bleeding • Dryness/thick, white discharge | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

General wellbeing:

- Feeling sick (nausea), tired (fatigue) or weak
- Cough, headache
- Trouble sleeping (insomnia) or feeling sleepy (drowsy)
- Sweating, feeling thirsty
- Changes to appetite or weight
- Hair loss
- Feeling anxious, nervous, annoyed, or sad
- Trouble remembering things

Skin/soft tissue problems:

- Dry, itchy, red, irritated skin/eyes
- Hot flushes
- Dry or sore mouth, ulcers (mouth sores), cold sores

Signs of urinary tract infection

- Pain when going to the toilet
- Going to the toilet more often

Muscle or joint problems:

- Back/breast/muscle/joint pain
- Pain in arms and legs, stiffness
- Arthritis, carpal tunnel, or trigger finger (finger bent and stuck)

Balance problems:

- Feeling dizzy, vertigo, falls

Serious side effects

| Serious side effects | What to do |
|---|---|
| <p>Heart problems:</p> <ul style="list-style-type: none"> • Fast or irregular heartbeat • Increased blood pressure • Crushing chest pain or sudden shooting arm or leg (foot) pain (signs of a heart attack) <p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • Trouble breathing, wheezing | <p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of</p> |

- Spreading rash, red skin, blistering of the lips, eyes or mouth, skin peeling (signs of skin disorder)
- Swelling of the face and throat.

Liver and kidney problems:

- Yellow skin or eyes (jaundice) Very dark wee or unable to wee

Vision problems:

- Blurry vision (cataract) or blindness

Blood or circulation problems:

- Weakness or being unable to move limbs or face, difficulty speaking/slurred speech, problems balancing or moving properly (signs of stroke)
- Swelling and redness along a vein which is extremely tender, painful to touch
- Numbness or painful swelling/ tingling in hands or feet, limbs
- Bluish skin, coughing up blood, fainting
- Swelling of the feet, ankles, or other parts of the body due to fluid build-up (signs of oedema)

Infections

- Flu-like symptoms including fever, chills, sore throat, general lack of energy or tiredness
- Feeling constantly sick, sores in mouth

Bone and connective tissue problems:

- Thinning of bones (osteoporosis), bone fractures
- Tendon disorders including tendonitis (inflammation of the tendon) and tenosynovitis (inflammation of the tissue surrounding the tendon): pain, swelling and tenderness near a joint.
- Tendon tears: feel a snap or pop when the tear happens, severe pain, swelling.

these serious side effects.

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

PHARMACOR LETROZOLE is available in tablets containing 2.5 mg of the active ingredient, letrozole.

What PHARMACOR LETROZOLE contains

| | |
|---|---|
| Active ingredient (main ingredient) | letrozole |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • Lactose monohydrate • 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, Macrogol 400 & Talc - purified) |
| Potential allergens | Pharmacor Letrozole 2.5 does not contain sucrose, gluten, tartrazine or any other azo dyes. |

Do not take this medicine if you are allergic to any of these ingredients.

What PHARMACOR LETROZOLE looks like

Pharmacor Letrozole 2.5 are yellow, round, biconvex, filmcoated tablets plain on both sides, supplied in blister pack and each pack contains 30 tablets. (AUST R 159589)

Who distributes PHARMACOR LETROZOLE

Pharmacor Pty Ltd

Suite 803, Tower A, The Zenith

821 Pacific Highway,

Chatswood NSW 2067 Australia

Web: www.pharmacor.com.au

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