

# LETROZOLE RBX TABLETS

Letrozole

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about **LETROZOLE RBX** tablets.

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.**

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking **LETROZOLE RBX** against the benefits it is expected to 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 LETROZOLE RBX is used for

**LETROZOLE RBX** is 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.

**LETROZOLE RBX** contains the active ingredient letrozole. Letrozole tablets are used to treat breast cancer in postmenopausal women, that is, women who no longer have periods, either naturally due to their age or after surgery or chemotherapy.

Letrozole belongs to a class of medicines known as aromatase inhibitors. They are also called "anti-oestrogens" because they block production of the hormone, oestrogen.

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 "anti-oestrogen" such as letrozole or you may have taken another "anti-estrogen" such as tamoxifen in the past.

**Ask your doctor if you have any questions about why LETROZOLE RBX has been prescribed for you.**

Your doctor may have prescribed **LETROZOLE RBX** for another reason.

**LETROZOLE RBX** is available only with a doctor's prescription.

### Before you take LETROZOLE RBX

#### *When you must not use it*

**Do not take LETROZOLE RBX if you are allergic to letrozole or any of the other ingredients of LETROZOLE RBX 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 difficulty in breathing.

**Do not take LETROZOLE RBX 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 the postmenopausal status is fully established.**

**Do not take LETROZOLE RBX if you are pregnant or breast-feeding.**

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

**If you are not sure whether you should start taking LETROZOLE RBX, talk to your doctor or pharmacist.**

**Do not take LETROZOLE RBX after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.** If you take this medicine after the expiry date has passed, it may not work as well or it may make you unwell.

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

#### *Before you start to take it*

**Tell your doctor if you have liver disease (yellowing of skin and whites of eyes with decreased appetite, abdominal pain) or kidney disease.**

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

You must also tell your doctor if you:

- **suffer from a disease of the bone that leads to loss of bone protein and minerals (osteoporosis) resulting in an increased risk of fracture and/or you have had a history of recurrent fractures**
- **have not yet gone through menopause.**

Your level of hormones may be checked by your doctor before you take **LETROZOLE RBX** to ensure you have gone through the menopause (cessation of periods).

**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 or pharmacist about any of the above, please do so before you take LETROZOLE RBX.**

#### *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 **LETROZOLE RBX** or they may affect how well it works.

Your doctor or pharmacist can tell you what to do when taking **LETROZOLE RBX** with other medicines. This includes in particular:

- tamoxifen
- other anti-estrogens or estrogen-containing therapies

These substances may diminish the action of **LETROZOLE RBX**.

#### **Women of child-bearing potential**

If you still until recently had menstrual periods, you should discuss with your doctor about the necessity of effective contraception as you might have the potential to become pregnant.

### HOW to take LETROZOLE RBX

**Follow all directions given to you by your doctor or 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 **LETROZOLE RBX** tablet daily.

#### *How to take it*

Swallow the tablet whole 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*

Your doctor will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

**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 your dose as soon as you remember, and then go back to taking your medicine as you would normally.**

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

#### *If you have taken too much (Overdose)*

**If you have taken too much, immediately telephone your doctor or the Poisons Information Centre (Tel. No. 13 11 26) for advice, or go to Accident & Emergency at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these numbers handy in case of an emergency.**

### While you are taking LETROZOLE RBX

#### *Things you must do*

**If you become pregnant while taking LETROZOLE RBX, 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 how well the medicine works and to 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 start on any new medicine, remind your doctor and pharmacist that you are taking LETROZOLE RBX.**

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

**This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking LETROZOLE RBX.**

*Things you must not do*

- Do not use **LETROZOLE RBX** to treat any other complaints unless your doctor tells you to.
- 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 LETROZOLE RBX 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.

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## Side Effects

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

Letrozole may have unwanted side effects in some people in addition to its beneficial effects. 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 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 up blood, rapid heartbeat, bluish skin discolouration, fainting.
- 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.
- Swelling mainly of the face and throat (signs of allergic reaction).
- Weakness or paralysis of limbs or face, difficulty speaking (signs of stroke).
- Crushing chest pain or sudden arm or leg (foot) pain (signs of a heart attack).

- Swelling and redness along a vein which is extremely tender, possibly painful to touch (signs of thrombophlebitis).

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

**Tell your doctor straight away if you experience any of the following:**

- 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).
- Blurred vision (sign of cataract).
- Swelling of the feet, ankles or other parts of the body due to fluid build-up (signs of oedema).

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

- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis
- high level of cholesterol
- 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 (feeling sad)
- drowsiness
- forgetfulness
- blurred vision or eye irritation
- stomach upset, nausea (feeling sick) or vomiting, indigestion, pain in the abdomen
- constipation
- diarrhoea
- dry mouth, sore mouth, mouth ulcers and cold sores
- thirst, change in sense of taste, dry mouth
- dry mucous membranes of the mouth, nose, vagina
- breast pain
- hot flushes
- increased sweating
- appetite changes
- increase or decrease in weight
- hair thinning
- urgent need to urinate (pass water)
- pain or burning sensation when urinating, which may be a sign of infection
- pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- fast or irregular heartbeats, palpitations, high blood pressure (hypertension)
- thinning of bones (osteoporosis), bone fractures
- cough
- trigger finger, a condition in which your finger or thumb catches in a bent position

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

Other side effects not listed above may also occur in some people.

Some of these can only be found by laboratory testing.

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## After using LETROZOLE RBX

### Storage

**Keep your tablets in the container until it is time to take them.**

**Store the tablets in cool dry place below 25°Celsius. Do not store LETROZOLE RBX 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. LETROZOLE RBX will keep well if it is in cool and dry place.

**Keep LETROZOLE RBX where children cannot reach it.**

A locked cupboard at least one and a half metres (1.5 m) above the ground is a good place to store medicines.

### Disposal

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

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## Product description

### What LETROZOLE RBX looks like

**LETROZOLE RBX** 2.5 mg tablets are yellow, round, biconvex, film-coated tablets with 'LETI' on one side and plain on the other side; available in blister packs of 30 tablets.

### Ingredients

**Active ingredient:**

2.5 mg of letrozole

**Inactive ingredients:**

- Lactose,
- maize starch,
- hypromellose,
- microcrystalline cellulose,
- sodium starch glycollate,
- colloidal anhydrous silica,
- magnesium stearate,
- macrogol 6000,
- titanium dioxide,
- purified talc and
- iron oxide yellow CI77492.

**LETROZOLE RBX** does not contain sucrose, gluten, tartrazine or any other azo dyes.

### Sponsor

**LETROZOLE RBX** is supplied in Australia by:  
**Ranbaxy Australia Pty Ltd.**  
9-13 Waterloo Road  
Macquarie Park NSW 2113  
AUSTRALIA

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AUST R 167832

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