

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LETRAZ, letrozole 2,5 mg film-coated tablets.

Sugar free.

Read all of this leaflet carefully before you start taking LETRAZ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- LETRAZ has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LETRAZ is and what it is used for
2. What you need to know before you take LETRAZ
3. How to take LETRAZ
4. Possible side effects
5. How to store LETRAZ
6. Contents of the pack and other information

1. What LETRAZ is and what it is used for

Letrozole is a medicinal product which forms part of a group called the aromatase inhibitors. These inhibitors block the production of oestrogens and are used for the treatment of breast cancer in postmenopausal women. They can be used either before surgery to reduce the size of the tumour, or after surgery to help prevent the tumour from returning. They can also be used in patients with advanced breast cancer to help stop the tumour spreading to other parts of the body.

2. What you need to know before you take LETRAZ

Do not take LETRAZ:

- if you are hypersensitive (allergic) to letrozole or to any of the other ingredients of LETRAZ (see section 6).
- if you are pregnant, suspect you are pregnant or while you are breastfeeding.
- if you have not yet gone through the menopause (if you still have periods).
- if you have a serious liver disease.
- if you have a serious kidney disease.

LETRAZ is not suitable for either children or men.

Warnings and precautions

Take special care with LETRAZ:

- if you have any liver or kidney disease
- when taking LETRAZ it may reduce the levels of female hormones which can lead to a loss of minerals in bones, and therefore cause a decrease in bone density and strength (osteoporosis). Your doctor may want to measure your bone density before and during your treatment
- women who previously suffered from a heart disease (specifically reduced blood supply to the heart), may have an increased risk for developing heart and blood vessel side effects.

Other medicines and LETRAZ

Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).

LETRAZ decreases liver enzymes responsible for the breakdown of certain medicines. Caution should be used when medicines which are dependent on these enzymes (e.g. antipsychotic medicine) are used together with LETRAZ.

The combination of tamoxifen (an estrogen receptor blocker) and LETRAZ may decrease the efficacy of LETRAZ due to reduced blood concentrations.

LETRAZ with food and drink

You may take LETRAZ with or without food, preferably with a glass of water.

Pregnancy and breastfeeding

You must not use LETRAZ during pregnancy, when you suspect you are pregnant or while you are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines

Do not drive or operate any tools or machinery until you know how LETRAZ affects you. LETRAZ may cause you to feel dizzy, tired or drowsy.

3. How to take LETRAZ

Do not share medicines prescribed for you with any other person.

Always take LETRAZ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of LETRAZ is 1 tablet once a day, by mouth.

Your doctor will tell you how long your treatment with LETRAZ will last. Do not stop treatment early as it can result in your tumour returning. You will probably continue to take LETRAZ tablets for a number of years.

If you have the impression that the effect of LETRAZ is too strong or too weak, tell your doctor or pharmacist.

If you take more LETRAZ than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take your medicine with you.

If you forget to take a dose of LETRAZ

If you forget to take a dose, take it as soon as you remember, then go on as before.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LETRAZ can have side effects.

Not all side effects reported for LETRAZ are included in this leaflet. Should your general health worsen while taking LETRAZ, please consult your doctor, pharmacist or other healthcare professional for advice.

Some side effects can be serious. If any of the following happens, stop taking LETRAZ and tell your doctor immediately or go to the casualty department at your nearest hospital.

Less frequent: Severe skin and / or allergic reactions, angina, heart attack, thrombosis, pulmonary embolism or stroke (see the symptoms below):

- heavy or tight chest or pain in the chest, spreading to your arms or shoulders, neck, teeth or jaw, abdomen or back
- coughing blood
- unusual pain or swelling of your arms or legs
- sudden shortness of breath, difficulty in speaking or breathing caused by blood clot in the lungs
- fainting
- numbness or weakness in your arm or leg or any part of your body caused by clotting in the blood vessels
- loss of co-ordination
- sudden severe headache
- severe rash or redness, which might include blistering and peeling and be accompanied by fever
- itching, swollen throat, tongue, face, eyelids or lips and difficulty in breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LETRAZ. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following frequently reported side effects:

- hot flushes
- joint pain (arthralgia)
- loss of appetite or increased appetite
- feeling of being sick, indigestion, constipation, diarrhoea

- weight gain
- raised cholesterol levels
- depression
- headache
- dizziness
- hair loss
- increased sweating
- muscle pain
- bone problems including pain, bone thinning (osteoporosis), and fractures
- feeling tired.

Less frequently reported side effects are:

- urinary tract infections, urinating more often
- tumour pain
- stomach pain
- general swelling due to fluid retention
- decreased white blood cells which can lead to increased infection occurrence (leukopenia)
- mental problems (anxiety, nervousness, irritability, loss of memory)
- sleep disturbances (sleepiness or difficulty in sleeping)
- changes in sensation, including touch sensation (pins and needles), taste changes
- eye problems such as cataract (loss of transparency of the lens of the eye), eye irritation, blurred vision, dry eyes
- heart abnormalities such as palpitations, fast heart beat (tachycardia), irregular heart beat (dysrhythmia), angina and heart attack (ischaemic cardiovascular disease)
- inflamed blood vessels
- high blood pressure
- breathlessness
- dry mouth or mouth ulcers

- liver problems, resulting in dark urine and yellowing of the eyes and skin
- dry or itchy skin or raised wheals
- arthritis (inflammation of the joints)
- vaginal bleeding, vaginal discharge, vaginal dryness
- fever
- thirst
- weight loss
- cough.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LETRAZ.

5. How to store LETRAZ

Store at or below 25 °C.

Do not remove blisters from outer container until required for use.

Protect from light.

Keep all medicines out of the reach and sight of children.

Do not use LETRAZ after the expiry date which is stated on the label and on the outer carton. The expiry date refers to the last day of the month.

Do not store in bathrooms.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What LETRAZ contains

The active substance is letrozole. Each film-coated tablet contains 2,5 mg letrozole.

The other ingredients are: magnesium stearate, polyethylene glycol, polyvinyl alcohol, silicified microcrystalline cellulose, sodium starch glycollate, sunset yellow FCF, talc, titanium dioxide and yellow iron oxide.

Sugar free.

What LETRAZ looks like and contents of the pack

Yellow, round biconvex, film coated tablets. Debossed "2,5" on one side, plain on reverse side.

LETRAZ is packed in clear PVC/PVdC silver aluminium blister strips packed in an outer carton. Each blister strip contains 10 film-coated tablets with 30 tablets per outer carton.

Holder of certificate of registration

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An electronic copy of the Professional Information (PI) is available on the Equity website

(<http://www.equitypharmaceuticals.co.za>)