Applicant : Eurolab (Pty) Ltd
Proprietary name : Laradex
Dosage form and strength : Film-coated tablets, 2,5 mg
Date of submission : 02 December 2024

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

LARADEX 2,5 Film Coated Tablets

Letrozole

Contains lactose

Read all of this leaflet carefully before you start taking LARADEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- **LARADEX** 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 **LARADEX** is and what it is used for
2. What you need to know before you take **LARADEX**
3. How to take **LARADEX**
4. Possible side effects
5. How to store **LARADEX**
6. Contents of the pack and other information

1. What LARADEX is and what it is used for

Letrozole, the active ingredient in LARADEX tablets, is one of a group of medicines called aromatase inhibitors. These block the production of oestrogens. LARADEX tablets are used to treat breast cancer in post- menopausal 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 LARADEX

Do not take LARADEX

- if you are hypersensitive (allergic) to letrozole or any of the other ingredients of LARADEX (listed in section 6).
- You have not gone through menopause,
- You are pregnant or breast feeding,
- You suffer from severe kidney or liver disease,
- You are a child.

Warnings and precautions

Special care should be taken with LARADEX:

- If you have kidney problems
- If you have liver problems
- If you have osteoporosis or bone fractures
- If you are premenopausal
- If you are taking any other oestrogen containing medication

Other medicines and LARADEX

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.) This means medicines you have bought yourself as well as medicines on prescription from your doctor.

- Do not take LARADEX with medicines such as ketoconazole, itraconazole, voriconazole, ritonavir, clarithromycin or telithromycin as these medicines increase the concentration of LARADEX.

- Do not take LARADEX with medicines such as phenytoin, rifampicin, carbamazepine, phenobarbital and St John's Wort, as these medicines decrease the concentration of LARADEX.
- The use of LARADEX with tamoxifen can reduce the concentration of LARADEX.

LARADEX with food and drinking

You are advised not to drink alcohol whilst taking these tablets since alcohol and LARADEX may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of LARADEX.

LARADEX may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

When pregnancy is detected, LARADEX should be discontinued as soon as possible.

Do not use LARADEX if you are pregnant or breast feeding your baby.

Driving and using machines

If you feel tired or dizzy when you start taking LARADEX do not drive or use machinery.

It is not always possible to predict to what extent LARADEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LARADEX affects them.

LARADEX contains lactose

LARADEX contains lactose. If you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take LARADEX

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

Always take LARADEX exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The doctor will decide what dose of LARADEX tablets you should take. Always take the tablets exactly as your doctor has told you to. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take, and how often. If you are not sure, ask your doctor or pharmacist.
Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

The usual dose of LARADEX is one tablet once a day. You will probably continue to take LARADEX for a number of years.

If you take more LARADEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you accidentally take too many LARADEX tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.
In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdosage can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take LARADEX

If you forget to take a dose, take it as soon as you remember. Then go on as before. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

If you stop taking LARADEX

Do not stop taking your tablets just because you feel better. It is important that you carry on taking LARADEX for as long as your doctor tells you.

If you have the impression that the effect of LARADEX is too strong or too weak, talk to your doctor or pharmacist.

4. Possible side effects

LARADEX can have side effects.

Not all side effects reported for LARADEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LARADEX, please consult your health care provider for advice.

If you notice any of the following serious side effects, stop having LARADEX and tell a doctor or contact the casualty department at your nearest hospital straight away:

- Angioedema that is the swelling of the blood vessels, swelling around the eyes, lips and tongue usually caused by a severe allergic reaction. The swelling can be itchy or painful.

The following side effects can occur:

Frequent

- No appetite for food, appetite increase, raised cholesterol levels
- Depression
- Headache, dizziness
- Nausea, vomiting, trouble digesting food with discomfort after meals, constipation, diarrhoea

- Baldness, increased sweating, rash
- Pain in a joint (arthralgia), muscular pain, bone pain, loss of calcium from bone tissue resulting in bones that break easily (osteoporosis), broken bones
- Hot flushes, tiredness, swelling of the extremities
- Weight increase
- Jaundice (yellowish eyes and/or skin)

Less Frequent:

- Infection of all organs that make and allow you to pass urine
- Tumor pain
- Too few white blood cells
- General swelling
- Anxiety
- Sleepiness, unable to sleep, memory loss, impairment of the senses, trouble tasting, stroke
- Clouding of the lens of the eye (cataract), eye irritation, blurred vision
- Rapid irregular action of heart, increased rate of heart beat
- Inflammation of a vein with clot formation, high blood pressure, heart attack, blood clot in the lung, formation of a solid mass in the arteries, stroke
- trouble breathing, cough
- Abdominal pain, inflammation of the inside of the mouth, dry mouth
- Increased liver enzymes
- Itchiness, dry skin, hives
- Inflammation of one or more joints (Arthritis)
- Urinating a lot more than usual
- Bleeding from the vagina, discharge from the vagina, dryness of the vagina, breast pain
- Fever, dryness of the mucous membrane, thirst
- Weight loss

- harmful effect on the skin resulting in death of skin cells, redness of the skin

Frequency unknown

- Swelling of the blood vessels, allergic reactions
- Inflammation of the liver
- harmful effect on the skin resulting in death of skin cells, redness of the skin
- Trigger finger (A condition in which a finger gets stuck in a bent position)

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LARADEX.

5. How to store LARADEX

Store at or below 25 °C. Do not remove the blisters from the outer container until required for use.

Store all medicines out of reach of children.

Store in original package.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What LARADEX contains

The active substance is 2,5 mg letrozole.

The other ingredients are:

- Colloidal anhydrous silica
- hydroxypropyl methylcellulose
- Iron oxide yellow
- lactose monohydrate
- magnesium stearate
- maize starch
- microcrystalline cellulose

What LARADEX looks like and contents of the pack

Yellow, round, biconvex, film coated tablets, plain on both sides.

LARADEX film coated tablets are packed in plain aluminium blister strips of 10 tablets per strip, with a clear PVC coated PVDC film. 3 strips of 10 tablets (30 tablets) are packed in a unit carton.

Holder of certificate of registration

Eurolab (Pty) Ltd.

Woodmead Office Park, 3 Stirrup Lane

Van Reenens Avenue

Woodmead

2144

This leaflet was last revised in

20 March 2025

Registration Number(s)

Laradex: 42/21.12/0324