LETARA™

Letrozole, 2.5 mg Film coated tablets

What is in this leaflet

What Letara™ is used for

Letara™ is used for the treatment of breast cancer in post- menopausal women i.e. women who no longer have periods, either because of their natural age or following surgery or chemotherapy.

Letara™ contains the active ingredient, 2.5 mg of letrozole and is presented in tablets.

This might be the first time you are taking an "antioestrogen" such as Letara™ or you might have taken another "antioestrogen" such as tamoxifen in the past.

If you have any questions about why Letara™ has been prescribed for you, ask your doctor.

You may have been prescribed Letara™ by your doctor for another reason.

Letara™ is only accessible with a doctor's prescription.

Letara™ is also not addictive.

How Letara™ works

Letrozole is an aromatase inhibitor – this family of medicines, which can be referred, also as "antioestrogens", function by decreasing the production of oestrogen in your body.

The growth of certain types of breast cancer is promoted by oestrogen. These cancers are known as "oestrogen- dependent". Decreasing the production of oestrogen may aid to prevent the cancer from growing.

Before you use Letara™

- When you must not use it

Do not take Letara™ if you are allergic to:

- Letrozole, the active ingredient in this medicine
- Any of the other ingredients of Letara™ as mentioned at the end of this Consumer Medicine Information leaflet.

If you get an allergic reaction, symptoms 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 Letara™ if you have not yet experienced menopause. This medicine is intended only to be used in post-menopausal women i.e. women who no longer have periods.

Do not use Letara™ if you are pregnant or breastfeeding unless your doctor says that it is safe.

Do not use Letara™ after the expiry date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Letara™ if the packaging is torn or shows signs of tampering. In such case, please return it to your pharmacist.

Do not use it to treat any other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else.

- Before you start to use it

If you have severe kidney or liver disease, you must tell your doctor. Your doctor might take special precautions while you are taking this medication.

If you are allergic to any other medicines, foods, dyes or preservatives, you must tell your doctor. Your doctor will need to know if you are allergy prone.

If you have not told your doctor any of the above things, please tell them before you begin taking Letara™.

- Taking other medicines

If you are on any other medicine, including medicine from a chemist, supermarket or health shop that you bought without a prescription, you must tell your doctor.

These medicines may affect the way Letara™ works.

Your doctor or pharmacist can tell you what to do if you are taking Letara™ with any other medicine.

How to use Letara™

Taking Letara™, follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, you must ask your doctor or pharmacist for help.

- How much to use

The usual dose is one Letara™ tablet taken per day.

Letara™ tablets should be swallowed whole with a glass of water or other liquid.

- When to use it

Letara™ should be taken around the same time every day. If you get an upset stomach after the taking the tablet, take it with a meal or after a snack.

- How long to use it

Continue taking Letara™ for as long as your doctor or pharmacist tells you.

Your progress will be checked by your doctor to ensure this medicine is working. Your doctor will make a decision on how long your treatment should continue.

Talk to your doctor if you are unsure.

- If you forget to use it

If you miss a dose, do not take an extra dose.

Just resume your normal schedule. For example, if you forget to take Monday's tablet leave the tablet allocated to Monday. Then on Tuesday resume as normal by taking the tablet allocated to Tuesday.

Do not take extra tablets to make up for a missed dose.

Ask your doctor or pharmacist for more hints if you have trouble remembering to take Letara™.

- If you use too much (overdose)

Immediately, telephone a doctor or Poisons Information Centre or go to the nearest Accident and Emergency department at your nearest hospital or clinic immediately if you think that you or someone else may have taken too much Letara™. Do this even if there are no signs of discomfort or poisoning.

While you are using it

- Things you must do

Tell your doctor immediately, if you become pregnant while taking Letara™. This medicine should not be taken while you are pregnant.

Your doctor's instructions should be followed carefully. If you do not, your treatment may not be helpful or you may have unwanted side effects.

Make sure you go to all of your doctor's appointments so that your progress can be checked. Your doctor may ask you to have blood tests from time to time to check on your progress and pick up any unwanted side effects.

Tell your doctor, dentist or pharmacist that you are on Letara™ if you are about to start taking any other new medicine.

Tell any other doctor, dentist or pharmacist who treats you that you are using Letara™.

LETARA™

Letrozole, 2.5 mg Film coated tablets

- *Things you must not do*

Do not use Letara™ to treat any other complaints unless your doctor says it is safe. Do not give this medicine to anyone else, even if they have the same symptoms as you.

- *Things to be careful of*

Be careful driving or operating machinery or doing other jobs which require you to be alert while you are taking Letara™ until you know how Letara™ affects you.

This medicine might cause dizziness or tiredness in some people. If you think that you have any of these symptoms, please 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 Letara™.

Letara™ helps most people, but it may have unwanted side effects in some people. All medicines have side effects. Sometimes they are serious but most of the time they are not. You may require medical treatment if you get some of the side effects.

Do not worry by the list of possible side effects. You may not even experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency department at your nearest hospital or clinic if you have any of the following:

- signs that blood clots could 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 thighs or calves, chest pain, difficulty in breathing, coughing
- continuous "flu-like" symptoms such as chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy, which could be signs of blood problems
- tightness or feeling of heaviness in the chest or pain radiating from your chest to your arms or shoulders, neck, teeth or jaw, abdomen or back (sign of heart attack or angina pectoris)
- numbness or weakness in arm or leg or any part of the body, loss of coordination vision changes, sudden headache, nausea, difficulty in speaking or breathing (sign of stroke)

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

Tell your doctor if you have any of the following side effects and they worry you:

- swelling of the feet, ankles or other parts of the body due to a build up of fluid
- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis
- headache
- fever
- fatigue
- tiredness, sleepiness, weakness or dizziness
- mood changes such as anxiety, nervousness, irritability and depression (sad mood)
- upset stomach, nausea (feeling sick) or vomiting, abdomen pain
- constipation
- diarrhea
- hot flushes
- increased sweating
- appetite or weight changes
- weight increase
- hair thinning
- thinning of bones (osteoporosis), leading to bone fractures in some cases
- high levels of cholesterol in the blood (hypercholesterolemia)

Tell your doctor if you have anything else that is making you unwell. Other side effects not listed above may occur in some people.

Some of these can be found only through laboratory testing.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Letara™

- *Storage*

- Keep your Letara™ tablets in the blister pack or bottle until it is time to take them
- Keep the Letara™ tablets in a cool dry place where the temperature stays below 30^{o}C
- Do not keep Letara™ or any other medicine in the bathroom or any other place that is hot or steamy
- Do not keep the tablets on window sills or in the car.

Both heat and dampness can destroy some medicines. Letara™ tablets will keep well if it is cool and dry.

Keep Letara™ tablets where children cannot reach them.

A good place to store medicines is in a locked cupboard at least one-and-a-half metres above the ground.

- *Disposal*

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product Description

- *What it looks like*

LETARA 2.5 mg tablets are yellow to dark yellow round, film coated, biconvex tablet, engraved with 'L' on one face and plain on the other.

- *Ingredients*

- Active ingredient(s)

Each LETARA contains 2.5 mg of the active ingredient, letrozole

- Inactive ingredients (Excipients)

colloidal anhydrous silica, microcrystalline cellulose, lactose monohydrate, magnesium stearate, maize starch, sodium starch glycollate, hydroxypropyl methylcellulose, polyethylene glycol 8000, talc, titanium dioxide (E 171), iron oxide yellow (E 172).

- *MAL number:*

MAL12095086AZ

Manufacturer

Douglas Pharmaceuticals Ltd
Central Park Drive, Lincoln Auckland,
PO Box 45 027, Auckland 0651,
New Zealand

Product Registration Holder

Schmidt BioMedTech Sdn Bhd
5th Floor, Wisma Tecna
No. 18A, Lot 318, Jalan 51A/223,
46100 Petaling Jaya, Selangor, Malaysia.

Date of revision

02/05/2024

Serial Number

NPRA(R2/1)240510/1270

308294