

Lebreta 2.5mg

(Letrozole Tablets)

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

1. What *Lebreta Tablet* is used for
2. How *Lebreta Tablet* works
3. Before using *Lebreta Tablet*
4. How to use *Lebreta Tablet*
5. While you are using it
6. Side effects
7. Storage and Disposal of
8. *Lebreta Tablet*
9. Product Description
10. Manufacturer and Product Registration Holder
11. Date of revision

What *Lebreta Tablet* is used for

Letrozole is used to treat breast cancer in women who have gone through menopause i.e. cessation of periods.

It is used to prevent cancer from happening again. It can be used as first treatment before breast cancer surgery in case immediate surgery is not suitable or it can be used as first treatment after breast cancer surgery or following five years treatment with tamoxifen. Letrozole is also used to prevent breast tumour spreading to other parts of the body in patients with advanced breast cancer.

If you have any questions about how Letrozole works or why this medicine has been prescribed for you, ask your doctor.

How *Lebreta Tablet* works

Lebreta contains an active substance called letrozole. It belongs to a group of medicines called aromatase inhibitors. It is a hormonal (or “endocrine”) breast cancer treatment. Growth of breast cancer is frequently stimulated by oestrogens which are female sex hormones. Letrozole reduces the amount of

oestrogen by blocking an enzyme (“aromatase”) involved in the production of oestrogens and therefore may block the growth of breast cancer that needs oestrogens to grow. As a consequence tumor cells slow or stop growing and/or spreading to other parts of the body.

Before use *Lebreta Tablet*

- When you must not use it

Do not take *Lebreta*:

- if you are allergic to Letrozole or any of the other ingredients of this medicine (listed in **Product Description**)
- if you still have periods, i.e. if you have not yet gone through the menopause
- if you are pregnant, trying to get pregnant or think you may be pregnant.
- if you are breastfeeding

If any of these conditions apply to you, do not take this medicine and ask your doctor or pharmacist for advice before taking any medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

- Before using *Lebreta Tablet*

Follow all the doctor's or pharmacist's instructions carefully. They may differ from the general information in this leaflet.

Refer to your doctor or pharmacist should you don't understand the instruction on your drug's labelling.

- Taking other medicines

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

How to use *Lebreta Tablet*

- How much to take

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose is one tablet of *Lebreta* to be taken once a day.

- When to take it

Use as directed by your doctor or pharmacist.

- How long to take it

Continue taking *Lebreta* for as long as your doctor recommends.

- If you forget to take it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you take too much (Overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Lebreta*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Lebreta* to anyone else, even if they have the same symptoms or condition as you.

- Things you must be careful of

Driving and using machine:

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Lebreta contains lactose:

Lebreta contains lactose (milk sugar). If you have been told by your doctor that you have intolerance to some sugars,

contact your doctor before taking this medicine.

Side effects

Like all medicines, *Lebreta* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Lebreta is generally well tolerated. The observed side effects are mainly mild or moderate in nature, and most are associated with estrogen deprivation.

The most frequently reported side effects were hot flushes, joint pain, nausea, increased sweating, high cholesterol and fatigue. Many side effects can be attributed to the normal consequences of estrogen deprivation (e.g. hot flushes, hair loss and vaginal bleeding).

Some common side effects are:

- loss of appetite or increased appetite
- high cholesterol levels
- depression
- headache
- dizziness
- nausea, vomiting
- indigestion
- constipation
- diarrhoea
- stomach pain
- hair loss
- increased sweating
- rash
- dry skin
- joint pain
- muscle pain
- bone pain
- osteoporosis
- bone fractures
- hot flushes

- fatigue
- swollen limbs (peripheral oedema)
- increased weight

If you experience any of these side effects in the list or not in the list, please inform your doctor.

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 *Lebreta* Tablet

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light.

Keep your medicine in the original package. If you take it out of its original package it may not keep well.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Lebreta Tablet is yellowed coloured, round shaped tablets debossed with 'LC' on one side and plain on the other side.

- Ingredients

- Active ingredient:

Lebreta Tablet: Each tablet contains 2.5 mg of Letrozole

- Inactive ingredients:

- Sodium Starch Glycolate
- Lactose Monohydrate
- Microcrystalline Cellulose
- Pregelatinized Starch
- Colloidal Silicone Dioxide
- Magnesium Stearate
- Opadry Yellow

- MAL number:

MAL14125128AZ

**Product Registration
Holder & Manufacturer**

Duopharma HAPI Sdn. Bhd.
No. 2, Jalan Saudagar U1/16,
Pusat Perindustrian Hicom
Glenmarie, Seksyen U1,
40150 Shah Alam,
Selangor Darul Ehsan, Malaysia

Date of revision

30/12/2021

Serial Number

NPRA(R2/1)191015/268