Patient Information Leaflet

Information for the Patient about

CIPLA-LETROZOLE 2.5

Read all of this leaflet carefully before you start taking CIPLA-LETROZOLE.

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **CIPLA-LETROZOLE 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.**

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLA-LETROZOLE 2.5 (Film-coated tablet)

WHAT CIPLA-LETROZOLE CONTAINS:

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

Inactive ingredients include lactose monohydrate, sodium starch glycollate, microcrystalline cellulose, hypromellose, colloidal silicon dioxide, magnesium stearate, and opadry yellow.

WHAT CIPLA-LETROZOLE IS USED FOR:

CIPLA-LETROZOLE is used to treat certain types of breast cancer in postmenopausal women provided that certain conditions are met. Your doctor will decide whether or not you qualify for treatment with **CIPLA-LETROZOLE**.

BEFORE YOU TAKE CIPLA-LETROZOLE:

Do not take CIPLA-LETROZOLE if you:

- Are hypersensitive or allergic to letrozole or any of the inactive ingredients.
- Have not yet reached menopause or have not completed your menopause.
- Are pregnant or breast feeding.
- Suffer from severe impairment of liver function. Your doctor will make this diagnosis.
- Suffer from severe impairment of kidney function. Your doctor will make this diagnosis.

Take special care with CIPLA-LETROZOLE:

If you have been diagnosed with osteoporosis (low bone mineral density) or your doctor has previously told you that you are at risk of osteoporosis, you will have to go for a bone density scan before you start treatment with **CIPLA-LETROZOLE** and at regular intervals while you are taking **CIPLA-LETROZOLE**. **CIPLA-LETROZOLE** may cause

a significant decrease in bone mineral density and your doctor may prescribe medicines to prevent or treat osteoporosis.

Taking CIPLA-LETROZOLE with food and drink:

CIPLA-LETROZOLE may be taken with or without food.

Pregnancy and breast feeding:

You should not take **CIPLA-LETROZOLE** if you are pregnant or breast feeding (please see **"Do not take CIPLA-LETROZOLE if you"**).

If you are pregnant or breast feeding your baby while taking CIPLA-LETROZOLE, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

You may experience fatigue, dizziness or excessive sleepiness while taking **CIPLA-LETROZOLE**. Your ability to drive a car or operate machinery may therefore be impaired. If you experience any of these side-effects, you should refrain from driving a car or operating machinery where loss of concentration may lead to accidents.

Important information about some of the ingredients in CIPLALETROZOLE:

CIPLA-LETROZOLE contains lactose. If you are lactose intolerant and you take **CIPLA-LETROZOLE**, you may experience unwanted side-

effects, such as nausea, cramping, bloating, diarrhoea (runny stomach), and flatulence. You should not take **CIPLA-LETROZOLE** if you have been diagnosed with hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption.

Taking other medicines with CIPLA-LETROZOLE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of CIPLALETROZOLE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE CIPLA-LETROZOLE:

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

The usual dose is one **CIPLA-LETROZOLE** tablet (2,5 mg) once daily. Your doctor will decide how long treatment with **CIPLA-LETROZOLE** should last. Treatment may last up to 5 years.

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

If you take more CIPLA-LETROZOLE than you should:

If you take more **CIPLA-LETROZOLE** than you should, or if somebody else takes your tablets by mistake, you or this other person may experience any of the side-effects listed below. **In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.**

If you forget to take CIPLA-LETROZOLE:

If you forget to take **CIPLA-LETROZOLE**, take it as soon as you remember. If you do not remember it until your next dose is due, skipped your missed dose and go back to your regular dosing schedule of one tablet once a day. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

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

Serious side-effects that you, or a family member, should report to your doctor as a matter of urgency include:

- Fever, chills, sore throat, coughing, pain in the flank, blood in the urine, or any other signs of infection, since this may be due to low white blood cell counts.
- Loss of consciousness or altered consciousness, weakness or very marked numbness suddenly affecting one side or one part of the body, severe headache, or paralysis of one side of the face or body as this may be due to a stroke.
- Severe central or left-sided chest pain that may or may not radiate to the chin or down the left arm accompanied by nausea and generally feeling unwell, as this may be due to a heart attack.
- Chest pain accompanied by shortness of breath or breathlessness, since this may be due to a blood clot in the lungs.
- Severe pain in a leg or arm accompanied by nausea, and pallor or bluish discoloration of the leg or arm.
- Shortness of breath.
- Bone fracture.
- Severe pain in the calf with or without swelling.

Other side-effects that you should report to your doctor as soon as possible include:

- Painful urination, burning urine, frequent urination or pain over the bladder area as this may indicate a bladder infection.

Blurred vision, red or watery eyes or eye discharge. Please report any deterioration in vision to your doctor as soon possible as this may be due to cataract formation.

- Palpitations or rapid heart rate.
- Pain, redness, and swelling of a blood vessel that is close to the skin.
- Ulcers on the lips or at the corners of the mouth.
- Any type of skin rash.
- Painful, red and swollen joints.
- Vaginal bleeding or vaginal discharge.
- Fever.

Please report any of the following side-effects to your doctor if they continue or become bothersome:

- Pain over the tumour area.
- Loss of appetite or increased appetite.
- Swelling of the feet, ankles, lower legs, hands or face.
- Depression, anxiety, nervousness or irritability.
- Headache or dizziness.
- Excessive sleepiness or inability to sleep, memory impairment, taste disturbance, and pins and needles or abnormal sensation.
- Nausea, vomiting, poor digestion, constipation, diarrhoea (runny stomach), stomach pain, or dry mouth.
- Hair loss, increased sweating, itching, dry skin or hives.
- Muscle pain, bone pain, joint pain.

- Vaginal dryness.
- Breast pain.
- Fatigue or generalised weakness.
- Swelling of the feet or ankles.
- Hot flushes.
- Dryness of the mouth or thirst.
- Weight loss or increase.

Other side-effects for which you will be monitored include:

- High blood cholesterol levels.
- High blood pressure.
- Abnormal liver function tests.
- Osteoporosis (low bone mineral density).

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

STORAGE AND DISPOSING OF CIPLA-LETROZOLE:

Store at or below 25 °C. Protect from moisture.

Keep blister in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

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

Return all unused medicine to your pharmacist.

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

PRESENTATION OF CIPLA-LETROZOLE:

Clear PVC/PE/PVDC on plain aluminium foil blister strips of 10 tablets packed in 30's.

IDENTIFICATION OF CIPLA-LETROZOLE TABLET:

Yellow, circular, biconvex film-coated tablets plain on both sides.

REGISTRATION NUMBER:

44/21.12/0282

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD Rosen Heights

Building 9

Parc du Cap, Mispel Street

7530

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