

PATIENT INFORMATION LEAFLET FOR
LANSOLOC OTC

Scheduling Status

S2

LANSOLOC OTC 15 mg capsules

Lansoprazole

Contains sugar: Sucrose 18,00 mg

Read all of this leaflet carefully because it contains important information for you.

LANSOLOC OTC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use LANSOLOC OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LANSOLOC OTC with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

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

1. What LANSOLOC OTC is and what it is used for

LANSOLOC OTC belongs to a group of medicines known as proton pump inhibitors, which reduces acid production in the stomach.

LANSOLOC OTC is used for the temporary, short-term relief of heartburn and increased acid (hyperacidity) of the stomach (see HOW TO TAKE LANSOLOC OTC).

2. What you need to know before you take LANSOLOC OTC

Do not take LANSOLOC OTC if you:

- are allergic (hypersensitive) to lansoprazole or to any of the inactive ingredients of LANSOLOC OTC.
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).
- if you have poor liver function
- if you are taking atazanavir or nelfinavir for Human Immunodeficiency Virus (HIV) infection (see **Other Medicines and LANSOLOC OTC**)

Warnings and Precautions

Take special care with LANSOLOC OTC:

- If you get a blistering rash on your skin (see **POSSIBLE SIDE EFFECTS**), especially in areas exposed to the sun, you should inform your doctor as soon as possible as you may need to stop your treatment with **LANSOLOC OTC**. Please inform your doctor about any pain in your joints.
- Treatment with **LANSOLOC OTC** may improve the symptoms of stomach ulcers, even if they are cancerous. It is important that you inform your doctor if you have recently experienced significant unintentional weight loss, recurrent vomiting, pain with swallowing, vomiting of blood or a substance resembling coffee grounds, or passed dark, foul-smelling,

tarry stools, before you take **LANSOLOC OTC**. Even if you consider your symptoms minor, it is important that you tell your doctor or pharmacist if you have noticed a change in your usual symptoms or if you are experiencing new symptoms.

- When receiving long-term therapy with **LANSOLOC OTC** your doctor may consider monitoring your magnesium levels. With a decrease in magnesium levels you may develop symptoms such as tiredness, confusion, involuntary contraction of muscles, dizziness, convulsions and abnormal heart rhythm. Please inform your doctor as soon as possible if you experience these symptoms. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
- Please inform your doctor as soon as possible if you have experienced pain in the hip, wrist or spine since this may be due to a bone fracture.
- Do not use **LANSOLOC OTC** for mild complaints, such as indigestion associated with tension or anxiety.
- Please consult your doctor if you develop severe and/or persistent loose stools (diarrhoea) while taking **LANSOLOC OTC** (see **POSSIBLE SIDE EFFECTS**). These symptoms may be due to inflammation of the large bowel (colon) and your doctor will have to decide whether you can safely continue to take **LANSOLOC OTC**.
- Please report to your doctor if you develop a combination of fever or chills, stomach pain or cramps, nausea, vomiting and loose stools with or without blood, since **LANSOLOC OTC** suppresses the secretion of stomach acid and you may therefore be more prone to develop infections involving the stomach and gut (see **POSSIBLE SIDE EFFECTS**).
- You have to wait at least two weeks after stopping **LANSOLOC OTC** before you can perform the urea breath test for *Helicobacter pylori* infection. Please discuss this with your doctor or pharmacist if you are unsure.

- You may develop a skin rash while taking **LANSOLOC OTC** (see **POSSIBLE SIDE EFFECTS**). These reactions, such as rashes, itching and hives, generally resolve when treatment with **LANSOLOC OTC** is stopped.
- While on treatment with **LANSOLOC OTC**, you may be at risk of developing a kidney disorder called interstitial nephritis, causing the inside of your kidneys to become inflamed. This condition may progress to renal failure as it is not necessarily reversed when treatment with **LANSOLOC OTC** is stopped (see **POSSIBLE SIDE EFFECTS**).

Children and adolescents

Do not give **LANSOLOC OTC** to your child, since it is not known whether **LANSOLOC OTC** is safe and effective in children.

Other medicines and LANSOLOC OTC

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

Please discuss the use of the following medicines in combination with **LANSOLOC OTC** with your doctor or pharmacist:

- Atazanavir or nelfinavir to treat HIV infection (see **What you need to know before you take LANSOLOC OTC**).
- Theophylline for asthma, emphysema or chronic bronchitis, as you may require a change in the theophylline dose when you start or stop taking **LANSOLOC OTC**.
- Warfarin, a blood thinner, as the combination of **LANSOLOC OTC** and warfarin may increase your risk of bleeding. You will have to go for blood tests to monitor your INR and/or prothrombin time.
- Methotrexate or tacrolimus, used to suppress the immune system.

- Fluvoxamine, an anti-depressant.
- Rifampicin, used for the treatment of tuberculosis (TB).
- St. John's wort (*Hypericum perforatum*), a herbal remedy used for mild depression.
- Oral contraceptives ("the pill").
- Carbamazepine for epilepsy.
- Sucralfate for stomach ulcers and acid reflux. **LANSOLOC OTC** should be taken at least 30 minutes prior to sucralfate.
- Antacids. **LANSOLOC OTC** should not be taken within 1 hour of a dose of antacids.
- Ketoconazole, itraconazole and voriconazole for fungal infections.
- Antibiotics, such as ampicillin or related compounds.
- Iron salts to treat iron deficiency anaemia.
- Digoxin for heart failure or heart rhythm disorders.
- Dasatinib for cancer.

LANSOLOC OTC with food, drink and alcohol

Take **LANSOLOC OTC** in the morning, 30 minutes before a meal (see **HOW TO TAKE LANSOLOC OTC**).

Pregnancy, breastfeeding and fertility

Do not take **LANSOLOC OTC** if you are pregnant or breastfeeding your baby.

If you are taking **LANSOLOC OTC** you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking LANSOLOC OTC.

Driving and using machinery

LANSOLOC OTC may lead to vision disturbances, drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other medicines (see **POSSIBLE SIDE EFFECTS**). Particularly when you start treatment, you should take care while operating vehicles or machinery, or performing potentially hazardous tasks where loss of vision or concentration could lead to accidents.

It is not always possible to predict to what extent **LANSOLOC OTC** 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 **LANSOLOC OTC** affects them.

LANSOLOC OTC contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **LANSOLOC OTC**.

Contains 18,00 mg sucrose per dose. This should be taken into account in patients with diabetes mellitus.

3. How to take LANSOLOC OTC

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

Always take **LANSOLOC OTC** exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Take one **LANSOLOC OTC** capsule once daily, for a maximum treatment period of 14 days.

Do not take more than 15 mg (one **LANSOLOC OTC** capsule) daily.

LANSOLOC OTC should preferably be taken before breakfast.

LANSOLOC OTC capsules should be swallowed whole with a glass of fluid. Under no circumstances should they be bitten, chewed or broken up.

If you have the impression that the effect of **LANSOLOC OTC** is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more LANSOLOC OTC than you should

In the event of an overdosage, you may experience any of the side effects listed below (see **POSSIBLE SIDE EFFECTS**).

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

If you forget to take LANSOLOC OTC

Always take **LANSOLOC OTC** as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one capsule once daily (every 24 hours). Do not take a double dose to make up for the forgotten individual dose.

4. Possible Side Effects

LANSOLOC OTC can have side effects

Not all side effects reported for **LANSOLOC OTC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LANSOLOC OTC**, please consult your doctor, pharmacist or other healthcare professional for advice.

The most frequently reported adverse events are headache, dizziness, fatigue, and feeling unwell (see **Take special care with LANSOLOC OTC**).

If any of the following happens, stop taking **LANSOLOC OTC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the lips, tongue, or face, skin rash with hives and/or itching, difficult breathing, and constriction of the throat, since any combination of these symptoms may be due to an allergic reaction.
- Fainting spells.
- rash or itching

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Those that occur less frequently:
 - Seeing or hearing things that are not real.
 - Fever or chills, coughing with the production of yellow, green or brown phlegm, or painful coughing.
 - Pale skin, shortness of breath upon exertion, unusual bleeding or bruising, unusual tiredness or weakness, bleeding from the gums, pin point red spots on the skin, easy bruising or blood in the urine, ulcers that will not heal, or a sore throat, as these symptoms may be due to low blood cell counts.
 - Seeing or hearing things that are not real.
 - Paralysis on one or both side(s) of the body, loss of consciousness or altered

consciousness, inability to speak, and/or loss of bladder or bowel control.

- Memory loss or confusion.
- Convulsions (seizures).
- Loss of vision, double or blurred vision.
- Loss of hearing.
- Chest pain going up the chin or down the left arm.
- Wheezing, tightness of the chest or shortness of breath.
- Coughing blood.
- Noisy breathing or whistling sounds when breathing.
- Watery, foul-smelling stools with or without blood in the stool (see **Take special care with LANSOLOC OTC**).
- Vomiting blood or severe stomach pain accompanied by the passage of black, tarry, foul-smelling stools (see **Take special care with LANSOLOC OTC**).
- Yellow discolouration of the skin or whites of the eyes, pain over the liver area with or without vomiting, and generally feeling unwell.
- Any blistering skin rash.
- Muscle weakness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Those that occur frequently:
 - Nausea, vomiting, or loose stools (see **Take special care with LANSOLOC OTC**).

- Headache.
- Constipation or stomach pain.
- Those that occur less frequently:
 - Fungal infection or thrush.
 - Painful urination, pain over the bladder area, frequent urination, discolouration of urine or blood in the urine.
 - Interstitial nephritis (kidney disease causing the inside of the kidney to become inflamed) which may progress to renal failure as it is not necessarily reversed when treatment is stopped.
 - Voice changes or hoarseness that persist for longer than 2 days.
 - Any abnormal growth on the skin or swelling of the lymph glands.
 - Excessive thirst or hunger accompanied by frequent urination and frequent infections.
 - Swelling of the thyroid gland (in front of the neck).
 - Severe pain, swelling and redness of a joint, such as that of the big toe.
 - Severe pain in the hip, wrist or spine.
 - Feeling hungry, weak or shaky with trembling hands.
 - Depersonalisation (feeling as if your thoughts and actions are not your own, feeling "unreal") or aggravated hostility.
 - Migraine.
 - Abnormal movements (hyperkinesia).
 - An abnormally acute sense of pain, heat, cold, or touch, tremor, or pins and needles.
 - Abnormal sense of taste or smell.

- Eye pain or sensitivity of eyes to light.
- Red or teary eyes or eye discharge (caking of the eyelids).
- Ear pain with or without a discharge.
- Palpitations.
- High blood pressure.
- Swelling of the feet, ankles or hands.
- Nose bleeds.
- Ulcers inside the mouth or on the lips, or inflammation of the tongue.
- Painful or difficult swallowing.
- Inability to pass stools.
- All other skin rashes, including a rash over areas exposed to the sun (see **Take special care with LANSOLOC OTC**).
- Painful, swollen joints.
- Vaginal discharge or itching, penile discharge or itching, or testicular pain.
- Milky discharge from the breasts or breast enlargement in men.
- Loss of appetite or increased appetite.
- Thirst.
- Weight gain or loss.
- Sleeplessness, sleepiness, abnormal dreams, agitation, anxiety, listlessness, or depression.
- Struggling to control your emotions, increased or decreased libido, nervousness, sleep disorder or abnormal thinking.
- Dizziness.

- Dry eyes.
- A sensation of motion when you are sitting or standing still or ringing in the ears.
- Feeling faint or dizzy after standing up or flushing (red discolouration of the skin).
- Hiccups.
- Sore throat, runny or blocked nose or pain over the sinuses.
- Dry mouth, bad breath, flatulence (gas) or belching/burping, bloating of the stomach, indigestion, increased salivation (more spit than usual), or feeling as if you constantly need to pass stools, even though your bowels are already empty.
- Acne, hair loss, dry skin, nail or hair disorders, or increased sweating.
- Muscle pain or cramps, or bone pain.
- Abnormal menstruation, breast pain or tenderness, painful menstruation, or impotence.
- Unusual tiredness or weakness, back or neck pain, flu-like symptoms, feeling unwell, or pain in the pelvic area.
- Those that occur with unknown frequency:
 - Tiredness, confusion, involuntary contraction of muscles, dizziness, convulsions and abnormal heart rhythm, since these may be due to low magnesium levels (see **Take special care with LANSOLOC OTC**). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of LANSOLOC OTC.

5. How to store LANSOLOC OTC

- Store in a cool, dry place, at or below 25 °C.
- Protect from light. Keep the blisters in the outer carton until required for use.

Store all medicines out of reach of children.

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 LANSOLOC OTC contains

The active substance is lansoprazole.

The other ingredients are

Pellet Core:

Light magnesium carbonate

Povidone

Polysorbate 80

Hydroxypropylcellulose

Maize starch

Purified talc

Sucrose

Non pareil seeds

Seal coating:

Hydroxypropylmethylcellulose

Purified talc

Enteric coating:

Eudragit L 100

Purified talc

Titanium dioxide

Polysorbate 80

Polyethylene glycol PEG

Colloidal silicon dioxide

Capsule Shell Composition:

Titanium dioxide – Colour Index No. 77891

Brilliant Blue – Colour Index No. 42090

Erythrosine – Colour Index No. 45430

Gelatin

SLS

What LANSOLOC OTC looks like and contents of the pack

LANSOLOC OTC: White to off - white, enteric coated pellets in hard gelatine capsule shells, size “3”, with blue cap and white body.

LANSOLOC OTC is presented in an outer carton containing an aluminium foil blister strip of 7 capsules, packed in 7's or 14's.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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