PATIENT INFORMATION LEAFLET

Information for the Patient about

LANSOLOC 30 (Capsules)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LANSOLOC 30 containing **lansoprazole** 30 mg (Capsules).

Read all of this leaflet carefully before you start taking LANSOLOC 30:

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **LANSOLOC 30 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 LANSOLOC 30 CONTAINS:

The active substance is lansoprazole.

Each **LANSOLOC 30** capsule contains 30 mg lansoprazole.

Inactive ingredients are colloidal anhydrous silica, colourants, gelatine, hydroxypropylcellulose, hypromellose, light magnesium carbonate, maize starch, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, povidone, purified talc, sodium hydroxide, sodium lauryl sulphate, sucrose, sugar spheres and titanium dioxide.

Contains sugar: Sucrose (37,8 mg)

WHAT LANSOLOC 30 IS USED FOR:

LANSOLOC 30 belongs to a group of medicines known as proton pump inhibitors, which reduces acid production in the stomach.

LANSOLOC 30 is used to treat ulcers of the stomach and first part of the small bowel (known as the duodenum) and inflammation of the oesophagus caused by reflux of stomach acid into the oesophagus (known as gastro-oesophageal reflux disease or GORD). Your doctor may prescribe antibiotics in combination with **LANSOLOC 30** for the treatment of ulcers of the duodenum.

BEFORE YOU TAKE LANSOLOC 30:

Do NOT take LANSOLOC 30 if:

- You are allergic (hypersensitive) to lansoprazole or to any of the inactive ingredients of **LANSOLOC 30**.
- You are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding"**).
- You have poor liver function.
- You are taking atazanavir for Human Immunodeficiency Virus (HIV) infection (see **"Taking LANSOLOC 30 with other medicines"**).

Take special care with LANSOLOC 30:

Do not give **LANSOLOC 30** to your child, since it is not known whether **LANSOLOC 30** is safe and effective in children.

Treatment with **LANSOLOC 30** 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 30**. Even if you consider your symptoms minor, it is important that you tell your doctor if you have noticed a change in your usual symptoms or if you are experiencing new symptoms.

Your doctor may decide that you require an endoscopic examination (swallow the scope). During this procedure a small piece of tissue may be taken from the stomach, oesophagus, or duodenum for examination under a microscope. This is called a biopsy and biopsies are necessary to rule out the possibility of cancer of the stomach or oesophagus.

When receiving long-term therapy with **LANSOPRAZOLE 30** 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.

Please inform your doctor as soon as possible if you experience pain in the hip, wrist or spine since this may be due to a bone fracture.

Do not use **LANSOLOC 30** 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 30** (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 30**.

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 30** 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 30** before you can perform the urea breath test for *Helicobacter pylori* infection. Please discuss this with your doctor if you are unsure.

You may develop a skin rash while taking **LANSOLOC 30** (see **"POSSIBLE SIDE-EFFECTS"**). These reactions, such as rashes, itching and hives, generally resolve when treatment with **LANSOLOC 30** is stopped.

While on treatment with **LANSOLOC 30** 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 30** is stopped (see **"POSSIBLE SIDE-EFFECTS"**).

Taking LANSOLOC 30 with food and drink:

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

Pregnancy and breastfeeding:

Do not take **LANSOLOC 30** while you are pregnant or breastfeeding your baby (see **"Do NOT take LANSOLOC 30"**).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking LANSOLOC 30.

Driving or using machinery:

LANSOLOC 30 may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other medicines. You should, particularly when you start treatment, take care while operating vehicles or machinery, or performing potentially hazardous tasks where loss of concentration could lead to accidents.

Important information about some of the ingredients of LANSOLOC 30:

LANSOLOC 30 capsules contain sugar/sucrose. You should not take **LANSOLOC 30** if you have been diagnosed with inborn fructose intolerance, glucose-galactose malabsorption syndrome or sucrose isomaltase deficiency. Please discuss this with your doctor if you are not sure.

Taking other medicines with LANSOLOC 30:

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 30** with your doctor or pharmacist:

- Atazanavir to treat HIV infection (see **"Do NOT take LANSOLOC 30"**).
- Theophylline for asthma, emphysema or chronic bronchitis, as you may require a change in the theophylline dose when **LANSOLOC 30** is started or stopped.
- Warfarin, a blood thinner, as combination of **LANSOLOC 30** 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 antidepressant.
- 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 30** should be taken at least 30 minutes prior to sucralfate.
- Antacids. **LANSOLOC 30** 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.

HOW TO TAKE LANSOLOC 30:

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

Always take LANSOLOC 30 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

LANSOLOC 30 should be taken once daily before breakfast.

LANSOLOC 30 capsules should be swallowed whole with a glass of fluid. Under no circumstances should they be bitten, chewed or broken up.

The usual dosage is 30 mg (one **LANSOLOC 30** capsule) per day for 2 to 4 weeks. Your doctor will calculate your dosage and decide how long treatment with **LANSOLOC 30** will last.

If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

If you have the impression that the effect of **LANSOLOC 30** is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more LANSOLOC 30 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 30:

Always take **LANSOLOC 30** 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 forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

LANSOLOC 30 can have side-effects.

Not all side-effects reported for LANSOLOC 30 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LANSOLOC 30, 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 30"**).

Serious side-effects that you, or a family member, should report to your doctor immediately include:

- Those that occur less frequently:
    - 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.
    - 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.
    - Fainting spells.
    - 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 30"**).
- Vomiting blood or severe stomach pain accompanied by the passage of black, tarry, foul-smelling stools (see **"Take special care with LANSOLOC 30"**).
- 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.

Side-effects that you should report to your doctor as soon as possible:

- Those that occur frequently:
  - Nausea, vomiting, or loose stools (see **"Take special care with LANSOLOC 30"**).
- 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.
- 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 stool.

- All other skin rashes, including a rash over areas exposed to the sun (see **"Take special care with LANSOLOC 30"**).
- Painful, swollen joints.
- Vaginal discharge or itching, penile discharge or itching, or testicular pain.
- Milky discharge from the breasts or breast enlargement in men.

- 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 30”**)

Side-effects that you should report to your doctor if they continue or become bothersome include:

- Those that occur frequently:
  - Headache.
  - Constipation or stomach pain.
- Those that occur less frequently:
  - 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, 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 disorder, 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 urea.

Please tell your doctor or pharmacist of any other undesirable effects that you think may be due to taking **LANSOLOC 30**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF LANSOLOC 30:

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.

Do not take the medicine after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF LANSOLOC 30:

White HDPE container of 14 and 28 capsules or outer carton containing an aluminium foil blister strip of 10 capsules, packed in 30's.

IDENTIFICATION OF LANSOLOC 30:

White to off-white, enteric-coated pellets in hard gelatine capsule shells, size '1', with red cap and white body.

REGISTRATION NUMBER:

37/11.4.3/0155

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

CIPLA MEDPRO (PTY) LTD

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Mispel Street

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