PATIENT INFORMATION LEAFLET

LANCAP RANGE

SCHEDULING STATUS

S4

LANCAP 15 mg capsules

LANCAP 30 mg capsules

Lansoprazole

LANCAP contains sugar (sucrose) in the following quantities:

LANCAP 15 mg (16,55 mg and sugar spheres 70,0 mg),

LANCAP 30 mg (33,10 mg and sugar spheres 140,0 mg)

Read all of this leaflet carefully before you start taking LANCAP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LANCAP 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 is in this leaflet

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

1. What LANCAP is and what it is used for

- LANCAP is used in the short-term treatment of gastric (stomach) and duodenal (small intestine) ulcers and inflammation of oesophagus due to reflux of stomach acid

- LANCAP is indicated for *Helicobacter pylori*-positive duodenal (small intestine) ulcers in conjunction with appropriate antibiotics as part of an eradication programme.

2. What you need to know before you take LANCAP

Do not take LANCAP:

- if you are hypersensitive (allergic) to lansoprazole, or to any of the ingredients of LANCAP (see section 6)
- if you are pregnant or breastfeeding your infant
- if you have severe liver impairment
- if you are on HIV medicines such as atazanavir or nelfinavir.

Warnings and precautions

Take special care with LANCAP:

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

- if you experience symptoms such as unintentional weight loss, recurrent vomiting, difficulty in swallowing, blood in vomit, dark sticky faeces or if you suspect a stomach ulcer tell your doctor because LANCAP can mask the symptoms of cancerous ulcers
- if you are using LANCAP over a long period of time (e.g. longer than 3 years) this may lead to a vitamin B_{12} deficiency
- as with all acid reducing medicines, LANCAP may affect the absorption of certain medicines such as vitamin C and calcium
- if you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as you can, as you may need to stop your treatment with LANCAP. Remember to also mention any other ill-effects like pain in your joints

- LANCAP may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD) (you may develop diarrhoea that does not stop). Contact your doctor or health care provider as soon as possible
- LANCAP may increase your risk for osteoporosis-related bone fractures of the hip, wrist or spine. Inform your doctor if you have osteoporosis
- if you have been told you have low magnesium levels in your blood, or if you experience fatigue, tetany (painful contractions of jaw and neck muscles), delirium, convulsions, dizziness and a change from normal heartbeat, or if you are taking medicines such as digoxin or diuretics (water tablets), tell your doctor as LANCAP can further reduce your magnesium levels
- if you are taking methotrexate (used in the treatment of cancer and leukaemia) as LANCAP may affect the way this medicine works
- if you are taking LANCAP for a long period of time, you may be at risk of gastro-intestinal infections such as *Salmonella*, and *Campylobacter, Shigella* or *Clostridium difficile*
- if you suffer from stomach ulcers you may be at risk of *H. pylori* (bacterial) infection
- LANCAP may make you drowsy and impair your concentration which could be aggravated by the intake of alcohol
- if you have porphyria, inform your doctor before taking LANCAP
- LANCAP may affect the kidneys (interstitial nephritis). Inform your doctor if you experience any pain while urinating or lower back pain
- if you take LANCAP on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor
- LANCAP may cause colitis (an inflammation of the colon) if you experience severe and/or persistent diarrhoea, you should stop taking LANCAP
- tell your doctor before taking LANCAP, if you are due to have a specific blood test (Chromogranin A) as it could interfere with the test results
- if there is a decrease in the amount that you usually urinate or if

- you have blood in your urine.

Children

Safety and efficacy in children has not yet been established.

Other medicines and LANCAP

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

LANCAP may affect the way the following medicines work:

- LANCAP can affect the absorption of these medicines: Itraconazole, ketoconazole, posaconazole, voriconazole (to treat fungal infections), ampicillin (antibiotic), iron supplements, atazanavir, nelfinavir (to treat HIV), dasatinib, erlotinib (to treat cancer)
- Methotrexate (to treat cancer)
- Digoxin (to treat heart problems)
- Warfarin (to prevent blood clots)
- Theophylline (to treat a tight chest)
- Tacrolimus (to prevent transplant rejection) may be intensified by LANCAP.

Medicines that may affect the way LANCAP works:

- If you are taking fluvoxamine (used to treat depression), the effect of LANCAP can be intensive
- St John’s Wort (to treat depression) and rifampicin (to treat TB)
- Sucralfate (to treat ulcers) or antacids (to treat heartburn)
- Antipyrine, indomethacin, ibuprofen, or other nonsteroidal anti-inflammatory drugs (NSAIDs); (medicines used to treat pain)
- Oral contraceptives

- Phenytoin (to treat epilepsy)
- Propranolol (to treat high blood pressure)
- Prednisone (to treat allergic reactions)
- Diazepam (to relax muscles or to treat anxiety)
- Clarithromycin (a type of antibiotic).

LANCAP may affect certain diagnostic tests for certain hormonal and nervous system tumours as well as the urea breath test for bacterial infections (*Helicobacter pylori*).

LANCAP with food and drink

If you take LANCAP within 30 minutes of food intake, it may result in lower lansoprazole plasma levels. Therefore, you should take LANCAP before meals, preferably in the morning.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take LANCAP while you are pregnant or breastfeeding your baby (see Do not take LANCAP).
If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before taking LANCAP.

Driving and using machines

LANCAP may impair your concentration and lead to drowsiness. If you simultaneously use alcohol or other central nervous system depressants, the drowsiness may be aggravated.
Do not take charge of vehicles or machinery or perform potentially hazardous tasks where loss of concentration could lead to accidents.

It is not always possible to predict to what extent LANCAP 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 LANCAP affects them.

LANCAP contains sugar

LANCAP contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LANCAP.

LANCAP contains sodium

LANCAP contains less than 1 mmol (0,023g) sodium per capsule, that is to say essentially 'sodium free'.

3. How to take LANCAP

Do not share medicines prescribed for you with any other person. Always take LANCAP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take LANCAP before a meal, preferably in the morning.

The usual dose is one LANCAP 15 mg or one LANCAP 30 mg capsule daily depending on the condition you are being treated for.

Your doctor will tell you how long your treatment with LANCAP will last. If you have the impression that the effect of LANCAP is too strong or too weak, tell your doctor or pharmacist.

If you take more LANCAP than you should

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 LANCAP

If you missed a dose, take it as soon as you remember. However, if it is almost time for your next dose, continue to take the next capsule at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking LANCAP

Do not stop treatment early because you start feeling better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

4. Possible side effects

LANCAP can have side effects.

Not all side effects reported for LANCAP are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using LANCAP, please consult your health care provider for advice.

If any of the following happens, stop using LANCAP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fever
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LANCAP. 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:

- yellowing of the skin and eyes, severe pain in your upper abdomen or your whole body starts itching, these are signs of severe liver problems including jaundice and hepatitis
- LANCAP may reduce the number of white cells in your blood, which may decrease your ability to fight infections

  If you experience any infection with symptoms such as fever or a serious deterioration in your general health, or a fever with symptoms such as sore throat/mouth, or bladder problems, you should see your doctor immediately
- chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, slower, harder or irregular, difficulty in breathing
- a persistent, scaly red patch on the skin with irregular borders that sometimes crusts or bleeds (skin cancer)
- Stevens-Johnson syndrome (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin) or other serious skin disorders
- serious kidney problems: less urine than is normal for you, swelling of the legs, ankles or feet, nausea or extreme tiredness, seizures or coma in severe cases
- if you experience symptoms of a stroke, such as weakness or numbness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking; dizziness, loss of balance; severe or prolonged headache with no known cause; loss of consciousness or fainting with or without seizure.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness
- diarrhoea, dry mouth or throat, nausea, vomiting (sometimes with blood), constipation, flatulence, stomach pain
- changes in liver test results (e.g. raised liver enzymes)
- itching, scaly red or purple inflamed skin or rash
- fatigue.

Less frequent side effects:

- changes in your blood cell count, or amount of sugar in your blood which may leave you feeling weak, tired, looking pale or generally feeling unwell, anaemia
- diabetes, goitre (swelling of the neck due to enlargement of the thyroid gland), underactive thyroid
- vitamin deficiency, dehydration, pain, stiffness or swelling in joints, extreme thirst, swelling of the hands or feet, neck or pelvic pain, neck or muscle stiffness, weight gain or loss, problems with smell or taste, muscle weakness or cramps
- abnormal dreams, mood changes such as agitation, hostility, memory loss, anxiety, laziness, confusion, a feeling of detachment from oneself, depression, mood swings, hallucinations (seeing or hearing things which are not there), increased or decreased sex drive, nervousness, distress, unable to sleep
- fit, double vision, paralysis on one side of the body, excessive abnormal body movements, stiff muscles, reduced sensitivity to touch, tingling or burning of the skin, restlessness, strange thoughts, sleepiness, tremor, vertigo (a sensation of spinning when standing still)
- abnormal or blurred vision, itchy, watery or red eyes, dry eyes, eye pain, sensitivity of eyes to the light, blurred vision and other problems with your vision including double vision
- deafness, ear problems, ear ache, ringing of the ears
- flushing, dizziness and feeling lightheaded, migraine, fainting

- difficulty in breathing/ tight chest, increased coughing, shortness of breath, nose bleed or coughing blood, hiccups, sore or scratchy throat or pain swallowing, sharp chest pain that gets worse when you breathe, runny or blocked nose, sinus headache, abnormal noise when breathing
- bleeding gums, increased appetite or saliva, mouth ulcer, blood in stool, abnormal tastes, anorexia, thirst, tongue disorder, pain inside the mouth due to white spots on your tongue, inner cheeks, gums, palate and/or tonsils, feeling that you need to have a bowel movement, even if you have already had one, inflammation of the mouth and lips, pancreatitis (upper abdominal pain that radiates into the back, which may be aggravated by eating foods high in fat)
- acne, hair loss, dry skin, problems with nails, sweating, sensitivity of skin to light, peeling of skin over large areas of the body
- painful, swollen or stiff joints, bone or joint problems, leg cramps, muscle or bone pain, muscle weakness, fracture of the wrist, hip or spine, neck pain or stiffness, pelvic pain, drooping of the upper eyelid, joint pain, bone disorder
- pain or discomfort on urination, blood in the urine, back pain (kidney pain), excessive or abnormally large production of urine, frequent urination or the need to constantly urinate, urinary tract infection
- a type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including LANCAP, may develop a kidney problem called acute interstitial nephritis, that can happen at any time during treatment with PPI medicines. Call your doctor right away if you have a decrease in the amount that you usually urinate or if you have blood in your urine
- abnormal periods (heavy, lighter, longer or more painful), breast enlargement or tenderness in both men and women, impotence, whitish or yellowish discharge, penis disorder or inflamed vagina
- feeling of weakness, chest pain, chills, fever, flu symptoms, smelly breath, infection, generally

feeling unwell, swelling or water retention

- increased sodium, cholesterol and triglyceride (fat) levels in the blood.

The following side effects have been reported but the frequency for them to occur is not known:

- decreased magnesium, calcium and potassium blood levels with symptoms such as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- If you get any of these symptoms, please inform your doctor promptly. 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, calcium and potassium.

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. By reporting side effects, you can help provide more information on the safety of LANCAP. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store LANCAP

Store all medicines out of reach of children.

Store in a dry place at or below 25 ºC.

Keep the capsules in the original container until required for use

Do not use after the expiry date stated on the carton. 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 LANCAP contains:

The active is lansoprazole.

LANCAP 15 mg: The active substance in each capsule is lansoprazole 15 mg.

LANCAP 30 mg: The active substance in each capsule is lansoprazole 30 mg.

The other ingredients are:

Disodium hydrogen phosphate dihydrate, gelatine capsules, macrogol, maize starch, methacrylic acid - ethyl acrylate copolymer (1:1), polysorbate, polyvinylpyrrolidone, sodium lauryl sulphate, sucrose, sugar spheres, talc, and titanium dioxide.

What LANCAP looks like and contents of the pack

LANCAP 15 mg: Capsules filled with white to light brown or slightly pink coloured pellets. The body of the hard gelatine capsule is white and the cap is red-brownish coloured.

LANCAP 30 mg: Capsules filled with white to light brown or slightly pink coloured pellets. The body and cap of the hard gelatine capsules are white.

LANCAP 15 mg capsules are available in white plastic bottles closed with a plastic tamper-evident cap containing 7, 14, 28 or 30 capsules.

LANCAP 30 mg capsules are available in white plastic bottles closed with a plastic tamper-evident cap containing 14, 28 or 30 capsules.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, 7945

Cape Town, South Africa

Tel.: +27 21 707 7000

or 0860-PHARMA (742 762)

This leaflet was last revised in

25 February 2026

Registration number

LANCAP 15 mg: A40/11.4.3/0247

LANCAP 30 mg: A40/11.4.3/0248

NAMIBIA

LANCAP 15 mg NS2 07/11.4.3/0098

LANCAP 30 mg NS2 07/11.4.3/0099