PATIENT INFORMATION LEAFLET

LANCAPT OTC

SCHEDULING STATUS

S2

LANCAP OTC 15 mg capsules.

Lansoprazole

LANCAP OTC contains sugar (sucrose 16,55 mg, sugar spheres 70,0 mg)

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

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

What is in this leaflet

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

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

The active ingredient in this medicine is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

LANCAP OTC is used in adults for the temporary short-term relief of heartburn and hyperacidity.

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

Do not take LANCAP OTC:

- if you are hypersensitive (allergic) to lansoprazole, or to any of the ingredients of LANCAP OTC
- if you are pregnant or breastfeeding your baby
- if you have severe liver disease
- if you are taking human immunodeficiency virus (HIV) medicines such as atazanavir or nelfinavir.

Warnings and precautions

Take special care with LANCAP OTC:

LANCAP OTC should not be taken by children as safety has not been established.

- 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 OTC can mask the symptoms, and delay diagnosis of cancerous ulcers
- LANCAP OTC may affect the kidneys (interstitial nephritis). Inform your doctor if you experience any pain while urinating or lower back pain
- if you take LANCAP OTC over a long period of time (e.g. longer than 3 years) this may lead to a vitamin B12 deficiency
- 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 OTC. Remember to also mention any other side effects like pain in your joints
- LANCAP OTC may cause diarrhoea that does not stop. Contact your doctor as soon as this occurs

- LANCAP OTC 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 OTC can further reduce your magnesium levels
- if you are taking methotrexate (used in the treatment of cancer and leukaemia) as LANCAP OTC may affect the way this medicine works
- LANCAP OTC should not be taken for longer than 14 days. If you take this medicine on a long-term basis there is an increased risk of gastric glandular cysts developing
- if you take LANCAP OTC for a long period of time, you may be at risk of gastrointestinal infections such as *Salmonella*, *Campylobacter, shigella* or *Clostridium difficile*
- if you suffer from stomach ulcers you may be at risk of *H. pylori* (bacterial) infection
- LANCAP OTC 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 OTC
- LANCAP OTC may cause colitis (inflammation of the colon). If you experience severe and/or persistent diarrhoea, you should stop taking LANCAP OTC
- tell your doctor before taking LANCAP OTC, if you are due to have a specific blood test (Chromogranin A) as it could interfere with the test results
- if you have a serious liver disease, ask your doctor for advice before taking LANCAP OTC.

Children

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Other medicines and LANCAP OTC

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

LANCAP OTC may affect the way the following medicines work:

- ampicillin (used to treat infections of the urinary and respiratory tracts) and iron salts (to prevent iron deficiency)
- HIV medicines atazanavir and nelfinavir
- ketoconazole and itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart failure)
- theophylline (used in the treatment of asthma, chronic bronchitis, emphysema)
- tacrolimus (to prevent transplant rejection)
- warfarin (used to treat blood clots)

Medicines that may affect the way LANCAP OTC works:

- fluvoxamine (used to treat depression and other psychiatric diseases)
- St John's Wort (to treat depression) and rifampicin (to treat tuberculosis (TB)
- sucralfate (to treat ulcers) or antacids (to treat heartburn)
- methotrexate (to treat cancer).

LANCAP OTC with food and drink

For the best effect of the medicine, you should take LANCAP OTC at least 30 minutes before a meal.

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 healthcare professional for advice before using

LANCAP OTC.

You should not take LANCAP OTC while you are pregnant or breastfeeding your baby (see Do not take LANCAP OTC).

Driving and using machines

LANCAP OTC may cause dizziness, vertigo, visual disturbances and drowsiness.

It is not always possible to predict to what extent LANCAP OTC may interfere with your daily activities.

You should avoid driving or use of machines until you are aware how LANCAP OTC affects you.

You should avoid driving or use of machines if you are experiencing dizziness, drowsiness or visual disturbances.

LANCAP OTC contains sugar

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

LANCAP OTC contains sodium

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

3. How to take LANCAP OTC

Do not share medicines prescribed for you with any other person. Always use LANCAP OTC exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is one 15 mg capsule in the morning, for no longer than 14 days.

Children:

LANCAP OTC is not indicated for use in children or adolescents under the age of 18 without a prescription by a doctor.

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

If you take more LANCAP OTC 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 OTC:

If you forget to take LANCAP OTC, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking LANCAP OTC

Do not stop treatment early because your symptoms have got 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 OTC can have side effects.

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

If any of the following happens, stop using LANCAP OTC 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
- fainting..

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

- if you experience 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
- if you experience rapid or irregular heartbeats, chest pain, angina, changes in the way your heart beats
- 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

- 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
- a persistent, scaly red patch on the skin with irregular borders that sometimes crusts or bleeds (skin cancer)

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:

- asthma, bronchitis, cough
- diarrhoea, dry mouth or throat, nausea, vomiting, constipation, stomach pain, flatulence
- abnormal liver test results
- skin rash, itching, a rash of round, red welts (hives)
- fatigue.

Less frequent side effects:

- oral or vaginal thrush (yeast infection), flu like symptoms, infections
- tumour of the larynx or voice box, stomach polyps — also called gastric polyps —(masses of cells that form on the lining inside your stomach)
- changes in your blood cell count 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, gout, changes in blood sugar levels, general swelling, weight gain or loss, anorexia

- abnormal dreams (nightmares), 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, dementia, (memory disorders, personality changes, and impaired reasoning), obsessive behaviour, hypochondria
- seizures or fits, 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, water or red eyes, dry eyes, eye pain, sensitivity of eyes to the light, blurred vision and other problems with your vision including double vision, conjunctivitis (pink eye), cataract
- deafness, ear problems, earache, ringing of the ears
- flushing, dizziness and feeling lightheaded, migraine
- difficulty in breathing/ tight chest, asthma, increased coughing, shortness of breath, nosebleed 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, 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 already have had one, abnormal stools, bloated abdomen, bleeding in the abdomen, bleeding of the gums, mouth ulcer, blood in the stools, 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, burning, or pricking feeling under the skin, bruising, reddening

- painful, swollen, or stiff joints, bone or joint problems, leg cramps, muscle or bone pain, back 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
- 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, smelly breath, 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:

- chronic, watery, non-bloody diarrhoea, gastric glandular cysts
- 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 OTC. 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 OTC

Store all medicines out of reach of children.

Store at or below 25 °C

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 OTC contains

The active substance is lansoprazolc 15mg.

The other ingredients are:

Disodium hydrogen phosphate dihydrate, gelatine capsules,macrogol, maize starch, methacrylic acid – ethyl acrylate copolymer (1:1) 30 % dispersion, polyethylene glycol 6000, polysorbate 80, povidone K-30, sodium lauryl sulphate, sucrose, sugar spheres, talc and titanium dioxide.

What LANCAP OTC looks like and contents of the pack

LANCAP OTC capsules are white/red-brownish (body: white, cap: red-brownish) capsules filled with white to light brown or slightly pink coloured pellets.

LANCAP OTC 15 mg capsules are available in white HDPE bottles closed with a polypropylene tamper-evident cap with mounted desiccant insert containing 14 capsules.

Holder of Certificate of Registration

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