LANCAP OTC

SCHEDULING STATUS S2

1. NAME OF THE MEDICINE
LANCAP OTC 15 mg capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains lansoprazole 15 mg.
Each capsule contains sugar (sucrose 16,55 mg, sugar spheres 70,0 mg).

For the full list of excipients, see section 6.1

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

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
LANCAP OTC is indicated in adults for the temporary short-term relief of heartburn and hyperacidity.

4.2 Posology and method of administration
Posology
LANCAP OTC should preferably be taken before a meal.
The maximum daily dose is 15 mg once daily for a maximum of 14 days.

Special populations
Elderly:
No dose adjustment is necessary. However, 15 mg per day is the maximum daily dose.

Renal impairment:
No dose adjustment is necessary in renal failure – this also applies to patients on dialysis.

Paediatric population
LANCAP OTC is not indicated for use in children as clinical data is limited.

Method of administration
LANCAP OTC should be taken at least 30 minutes before a meal (see section 5.2).
Capsules should be swallowed whole with liquid.

For patients with difficulty swallowing; the capsules may be emptied, but the contents may not be chewed or ground.

Missed dose:
Medical practitioners should advise patients who forget to take LANCAP OTC to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications
- hypersensitivity to lansoprazole or to any of the ingredients of LANCAP OTC
- pregnancy and lactation
- severe hepatic impairment
- LANCAP OTC is contraindicated with atazanavir or nelfinavir, as it substantially reduces exposure to the human immunodeficiency virus (HIV) protease inhibitor (see section 4.4).

4.4 Special warnings and precautions for use
Safety and efficacy in children:
Safety and efficacy in children have not been established.

Diagnosis of reflux oesophagitis:
Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Exclusion of malignant ulcers:
Treatment with LANCAP OTC may alleviate the symptoms of malignant ulcers and can delay diagnosis. Therefore, in the presence of symptoms such as, significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, or melaena, and when gastric ulcer is suspected or present, the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded prior to treatment with LANCAP OTC.

Occurrence of acute interstitial nephritis:
Acute interstitial nephritis has been observed in patients taking proton pump inhibitors (PPIs), including LANCAP OTC. Acute interstitial nephritis may occur at any point during therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue LANCAP OTC if acute interstitial nephritis develops (see section 4.3).

Malabsorption:
Daily treatment with acid-suppressing medicines such as LANCAP OTC over a long period of time (e.g. longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B12) caused by hypo- or achlorhydria. Cyanocobalamin deficiency occurring with acid-suppressing therapy has been reported. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed.
Proton pump inhibitors such as LANCAP OTC have also been reported to impair the bioavailability of dietary vitamin C. Fat malabsorption (secondary to increased deconjugation of bile acids caused by bacterial overgrowth in the jejunum) was reported when patients were treated with proton pump inhibitors such as LANCAP OTC. Proton pump inhibitors such as LANCAP OTC can cause calcium malabsorption (see Bone fracture).

Subacute cutaneous lupus erythematosus (SCLE):
Proton pump inhibitors such as LANCAP OTC are associated with cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the healthcare professional should consider stopping LANCAP OTC.
SCLE after previous treatment with a proton pump inhibitor such as LANCAP OTC may increase the risk of SCLE with other proton pump inhibitors.

Increased risk of Clostridium difficile associated diarrhoea:
LANCAP OTC may be associated with an increased risk of Clostridium difficile associated diarrhoea (CDAD). A diagnosis of CDAD should be considered for patients taking LANCAP OTC who develop diarrhoea that does not stop. Symptoms include watery stool, abdominal pain, and fever, and patients may go on to develop more serious intestinal conditions. Factors that may predispose an individual to developing CDAD include advanced age, certain chronic medical conditions, and taking broad spectrum antibiotics. Treatment for CDAD includes the replacement of fluids and electrolytes and the use of special antibiotics. Patients should use the lowest dose and shortest duration of LANCAP OTC therapy appropriate to the condition being treated.

Bone fracture:
LANCAP OTC therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term therapy (a year or longer) mainly in the elderly or in the presence of other recognised risk factors. Patients should use the lowest dose and shortest duration of LANCAP OTC therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines and should receive appropriate care (see section 4.8).

Occurrence of hypomagnesaemia, hypocalcaemia and hypokalaemia:
Severe hypomagnesaemia has been reported in patients treated with LANCAP OTC for at least 3 months to one year. hypomagnesaemia also produces impaired parathyroid hormone secretion which may lead to hypocalcaemia. Most patients had concomitant hypercalcaemia and normal parathyroid hormone levels; therefore it confirms hypomagnesaemia as the primary deficit. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular dysrhythmia can occur, but may begin slowly and be overlooked. In most patients affected, symptoms improved after magnesium replacement and discontinuation of LANCAP OTC.
For patients expected to be on prolonged treatment or who take LANCAP OTC with digoxin or medicines which may cause hypomagnesaemia (e.g. diuretics), healthcare professionals should consider measuring magnesium levels before starting and during treatment with LANCAP OTC (see section 4.8).
Lansoprazole decreases gastric acid secretion by targeting hydrogen (H)+, potassium (K)+-adenosine triphosphatase (ATPase) in acidic conditions, hypokalaemia is not generally introduced by LANCAP OTC alone, but in extreme alkalosis or an impaired K+ -recycling system, LANCAP OTC may cause hypokalaemia unrelated to hypomagnesaemia.

Concomitant use with methotrexate:
Concomitant use of LANCAP OTC with methotrexate (primarily at high doses) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of LANCAP OTC may be considered in some patients (see section 4.5).

Effects related to acid inhibition:
During long-term treatment, gastric glandular cysts have been reported in increased frequency. These physiological changes result from pronounced inhibition of gastric acid secretion.

Gastrointestinal infections caused by bacteria:
Decreased gastric acidity increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with LANCAP OTC may lead to an increased risk of gastrointestinal infections such as *Salmonella, Campylobacter, Shigella or Clostridium difficile.*

Helicobacter pylori (H. pylori):
In patients suffering from gastroduodenal ulcers, the possibility of *H. pylori* infection as an etiological factor should be considered.

Effect on central nervous system:
LANCAP OTC may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

Possible porphyrinogenicity:
Lansoprazole, as in LANCAP OTC, is possibly porphyrinogenic and should be used only when no safer alternative is available, and precautions should be considered in all patients.

Long term use:
Because of limited safety data for patients on maintenance treatment for longer than 1 year, regular review of the treatment should be performed in these patients.

Colitis*:*
Colitis has occurred in patients taking lansoprazole as contained in LANCAP OTC. Therefore, in the case of severe and/or persistent diarrhoea, discontinuation of therapy should be considered.

Interference with laboratory tests:
Increased Chromogranin A (CgA) levels may interfere with investigations for neuroendocrine tumours. To avoid this interference, LANCAP OTC treatment should be stopped for at least 5 days before CgA measurements (see section 5.1). If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

Information on excipients of LANCAP OTC:
Patients with rare hereditary problems such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take LANCAP OTC.

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

Paediatirc population
Safety and efficacy in children has not yet been established.

4.5 Interaction with other medicines and other forms of interaction
Effects of LANCAP OTC on other medicines
Medicines with pH dependent absorption:
LANCAP OTC may interfere with the absorption of medicines where gastric pH is critical to bioavailability (e.g. ampicillin esters, iron salts).

HIV Medicines:
It has been shown that co-administration of atazanavir with proton pump inhibitors such as LANCAP OTC results in a substantial reduction in the bioavailability of atazanavir. Therefore, LANCAP OTC must not be co-administered with atazanavir and nelfinavir (see section 4.3).

Ketoconazole and itraconazole:
The absorption of ketoconazole and itraconazole from the gastrointestinal tract is enhanced by the presence of gastric acid. Administration of lansoprazole, as in LANCAP OTC, may result in subtherapeutic concentrations of ketoconazole and itraconazole and the combination should be avoided.

Digoxin:
Co-administration of LANCAP OTC and digoxin may lead to increased digoxin plasma levels. The plasma levels of digoxin should therefore be monitored, and the dose of digoxin adjusted if necessary when initiating and ending LANCAP OTC treatment.

Medicines metabolised by cytochrome P450 (CYP450) enzymes:
LANCAP OTC may increase plasma concentrations of medicines that are metabolised by cytochrome P3A4 (CYP3A4). Caution is advised when combining LANCAP OTC with medicines which are metabolised by this enzyme and have a narrow therapeutic window.

Theophylline:
LANCAP OTC reduces the plasma concentration of theophylline potentially decreasing the expected clinical effect at the required dose.
Patients may require additional titration of the theophylline dosage when treatment with LANCAP OTC is commenced or discontinued, to ensure clinically effective blood levels. Caution is thus advised when used in combination.

Tacrolimus:
Co-administration of LANCAP OTC may cause an increase in tacrolimus (a CYP3A and P-glycoprotein (P-gp) substrate) plasma concentrations and result in a decreased clearance. Monitoring of tacrolimus plasma concentrations is advised when concomitant treatment with LANCAP OTC is initiated or ended.

Medicines transported by P-glycoprotein:
Lansoprazole, as in LANCAP OTC, has been observed to inhibit the transport protein, P-glycoprotein (P-gp) *in vitro*. The clinical relevance of this is unknown.

Effects of other medicines on LANCAP OTC
Medicines which inhibit CYP2C19:
Fluvoxamine:
Fluvoxamine may increase the plasma concentration of lansoprazole therefore a dose reduction may need to be considered in patients taking these medicines concomitantly.

Medicines which induce CYP2C19 and CYP3A4:
Enzyme inducers affecting CYP2C19 and CYP3A4 such as rifampicin, and St John's wort (*Hypericum perforatum*) can reduce the plasma concentrations of lansoprazole in LANCAP OTC.

Others
Warfarin:
There have been reports of increased international normalised ratio (INR) and prothrombin time in patients receiving PPIs such as LANCAP OTC and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with LANCAP OTC and warfarin concomitantly may need to be monitored for increase in INR and prothrombin time, especially when initiating or ending concomitant treatment.

Sucralfate/antacids:
The bioavailability and absorption of LANCAP OTC may be decreased with concomitant administration of sucralfate/antacids. LANCAP OTC should be taken at least 1 hour after taking these medications.

Nonsteroidal anti-inflammatory medicines:
No clinically significant interactions of LANCAP OTC with nonsteroidal anti-inflammatory medicines have been demonstrated, although no formal interactions studies have been performed.

Methotrexate*:*
Although lansoprazole as contained in LANCAP OTC has been reported not to affect the pharmacokinetics of methotrexate, concomitant use with high-dose methotrexate may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. Therefore, in settings where high-dose methotrexate is used a temporary withdrawal of LANCAP OTC may need to be considered.

4.6 Fertility, pregnancy and lactation
Pregnancy
LANCAP OTC is contraindicated in pregnancy and lactation (see section 4.3). Safety in pregnancy and lactation has not been established.
Adequate and well-controlled studies in humans have not been done.

Breastfeeding
It is not known whether lansoprazole, as contained in LANCAP OTC, is distributed into breast milk. However, lansoprazole or its metabolites are known to be distributed into the milk of rats. Lansoprazole has been shown to cause tumourigenic effects in animals and is therefore not recommended during breastfeeding (see section 4.3).

4.7 Effects on ability to drive and use machines
Adverse reactions such as dizziness, vertigo, visual disturbances and somnolence may occur when taking LANCAP OTC. Under these conditions the ability to react may be decreased. Patients should therefore be advised not to drive or operate machinery until they know how LANCAP OTC affects them.

4.8 Undesirable effects
a. Tabulated list of adverse reactions

System Organ Class	Frequency	Side effects
Infections and Infestations	*Less frequent*	Candidiasis, flu syndrome, infection
Neoplasms benign and malignant (including cysts and polyps)	*Less frequent*	Carcinoma, laryngeal neoplasia, skin carcinoma, gastric nodules, fundic polyps
Blood and lymphatic system disorders	*Less frequent*	thrombocytopaenia, anaemia, leukopaenia, neutropenia, eosinophilia, agranulocytosis, pancytopenia, haemolysis, lymphadenopathy
Immune system disorders	*Less frequent*	Allergic reaction, bronchospasm, angioedema, anaphylaxis, anaphylactic shock, acute interstitial nephritis
Endocrine disorders	*Less frequent*	Diabetes mellitus, goitre, hypothyroidism
Metabolism and nutrition disorders	*Less frequent*	Avitaminosis, dehydration, gout, hyperglycaemia/hypoglycaemia, peripheral oedema, weight gain/loss, anorexia
	Frequency unknown	Hypomagnesaemia: severe hypomagnesaemia can correlate with hypocalcaemia and may result in hypokalaemia
Psychiatric disorders	*Less frequent*	Abnormal dreams, agitation, amnesia, anxiety, apathy, confusion, depersonalisation, depression, emotional lability, hallucinations, hostility aggravated, libido decreased/increased, nervousness, sleep disorder, dementia, neurosis, insomnia
Nervous system disorders	*Frequent*	Headache, dizziness
	Less frequent	Convulsion, diplopia, hemiplegia, hypoesthesia, hyperkinesia, hypertonia, paraesthesia, restlessness, thinking abnormality, somnolence, parosmia, tremor, vertigo
Eye disorders	*Less frequent*	Abnormal vision, amblyopia, blepharitis, blurred vision, cataract, conjunctivitis, dry eyes, eye pain, photophobia, retinal degeneration, visual field defect, visual disturbances
Ear and labyrinth disorders	*Less frequent*	Deafness, ear disorder, otitis media, tinnitus
Cardiac disorders	*Less frequent*	Angina, dysrhythmia, bradycardia, myocardial infarction, palpitations, shock (circulatory failure), tachycardia, cardiospasm
Vascular disorders	*Less frequent*	Vasodilation, cerebrovascular accident/ cerebral infarction, hypertension/ hypotension, migraine, syncope
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Asthma, bronchitis, cough increased, dyspnoea, epistaxis, haemoptysis, hiccough, laryngeal neoplasia, pharyngitis, pleural disorder, pneumonia, respiratory disorder, upper respiratory inflammation/ infection, rhinitis, sinusitis, stridor, parosmia
Gastrointestinal disorders	*Frequent*	Diarrhoea, dry mouth or throat, nausea, vomiting, constipation, abdominal pain, flatulence
	Less frequent	Abnormal stools, anorexia, bezoar, cholelithiasis, colitis, dyspepsia, dysphagia, enteritis, eructation, faecal discolouration, gastric nodules/fundic gland polyps, gastritis, gastroenteritis, gastrointestinal anomaly, abdomen enlarged, gastrointestinal disorder, gastrointestinal haemorrhage, glossitis, gum haemorrhage, haematemesis, increased appetite, increased salivation, melena, mouth ulceration, oesophageal candidiasis, oesophageal stenosis, oesophageal ulcer, oesophagitis, oral moniliasis, rectal disorder, rectal haemorrhage, stomatitis, taste abnormalities, tenesmus, thirst, tongue disorder, ulcerative colitis, ulcerative stomatitis, pancreatitis (sometimes fatal)
	Frequency unknown	Collagenous colitis, gastric glandular cysts
Hepatobiliary disorders	*Frequent*	Elevation in hepatic enzymes
	Less frequent	Hepatitis, jaundice, liver injury, hyperbilirubinaemia, cholelithiasis
Skin and subcutaneous tissue disorders	*Frequent*	Skin rash, pruritus, urticaria
	Less frequent	Acne, alopecia, contact dermatitis, dry skin, erythema multiforme, fixed eruption, nail disorder, skin disorder, sweating, Stevens-Johnson syndrome or toxic-epidermal necrolysis, photosensitivity, petechiae, purpura, hair disorder, maculopapular rash
Musculoskeletal, connective tissue and bone disorders	*Less frequent*	Asthenia, arthralgia, arthritis, back pain, myalgia, fracture of the hip, wrist or spine, joint disorder, leg cramps, musculoskeletal pain, myasthenia, neck pain, neck rigidity, pelvic pain, ptosis, synovitis, bone disorder
Renal and urinary disorders	*Less frequent*	Dysuria, interstitial nephritis, kidney calculus, kidney pain, polyuria, urethral pain, urinary frequency, urinary tract infection, urinary urgency, urination impaired, urinary retention
Reproductive system and breast disorders	*Less frequent*	Abnormal menses, breast enlargement, breast pain, breast tenderness, dysmenorrhoea, gynaecomastia, impotence, leucorrhoea, menorrhagia, menstrual disorder, penis disorder, vaginitis, testes disorder, galactorrhoea
General disorders and administrative site conditions	*Frequent*	Fatigue
	Less frequent	Asthenia, chest pain, chills, fever, halitosis, malaise, oedema, pain
Investigations	*Less frequent*	Hyponatraemia, increase in cholesterol and triglyceride levels

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 OVERDOSE
Signs and symptoms:
The effects of overdose on lansoprazole as in LANCAP OTC, in humans are not known (although the acute toxicity is likely to be low). However, daily doses of up to 180 mg of lansoprazole orally and up to 90 mg of lansoprazole intravenously have been administered in trials without significant undesirable effects.
Refer to section 4.8. for possible symptoms of lansoprazole overdose.

Management of overdose:
Treatment is symptomatic and supportive. In the case of suspected overdose, the patient should be monitored. Lansoprazole, as contained in LANCAP OTC, is not significantly eliminated by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Proton pump inhibitors.
ATC code: A02BC03.
Pharmacological classification: A. 11.4.3 Medicines acting on the gastrointestinal tract – other.

Mechanism of action
Lansoprazole is an inhibitor of the gastric H^+ K^{+-}ATPase (proton pump). Lansoprazole inhibits gastric acid secretion in a dose related manner irrespective of the source of stimulation. Gastric secretory functions recover gradually following discontinuation of the medicine. Lansoprazole has no effect on histamine, gastrin or cholinergic receptors.

5.2 Pharmacokinetic properties
Absorption:
Following oral administration, lansoprazole is well absorbed with a resultant bioavailability of approximately 78 %. The bioavailability is decreased if lansoprazole is taken with food. Peak serum concentrations are achieved approximately 1 - 2 hours following ingestion.

Distribution:
Lansoprazole is highly protein bound (97 %).

Biotransformation:
Lansoprazole is extensively metabolised via the hepatic cytochrome P450 system to the inactive, sulphated metabolites – sulphone, sulphide and 5-hydroxyl-lansoprazole. The half-life for lansoprazole is 1,4 - 1,5 hours.

Elimination:
The main route of elimination is via the bile with 15 - 30 % of lansoprazole been excreted via the kidneys as the hydroxylated metabolite.

Pharmacokinetics in special patient groups
Elderly:
The clearance of lansoprazole is decreased in the elderly, with elimination half-life increased approximately 50 - 100 %. Because the mean half-life in the elderly remains between 1,9 - 2,9 hours, repeated once daily dosing does not result in accumulation of lansoprazole. Peak plasma levels are not increased in the elderly therefore no dose adjustment is necessary.

Renal impairment:
In patients with severe renal insufficiency, plasma protein binding decreases by 1,0 - 1,5 % after administration of 60 mg of lansoprazole. Patients with renal insufficiency have a shortened elimination half-life and decreased total AUC (free and bound). AUC for free lansoprazole in plasma, however, is not related to the degree of renal impairment, and C_{max} and T_{max} are not different from patients with healthy kidneys. No dosage adjustment is necessary in patients with renal impairment.

Hepatic impairment:
In patients with various degrees of chronic hepatic disease, the mean plasma half-life of lansoprazole is prolonged from 1,5 hours to 3,2 hours to 7,2 hours. An increase in mean area under the plasma drug concentration-time curve (AUC) of up to 500 % has been observed at steady state in hepatically-impaired patients compared to healthy patients. Dose reduction in patients with severe hepatic disease should therefore be considered.

Race:
The mean AUC of lansoprazole in Asian patients is approximately twice that observed in whites or African Americans, since the former population are more likely to have the CYP2C19 genotype that correlates with slow metabolism of proton pump inhibitors. This finding may contribute to heightened efficacy and/or toxicity in the Asian population.

CYP2C19 poor metabolisers:
CYP2C19 is subject to genetic polymorphism and 2 - 6 % of the population, called poor metabolisers (PMs), are homozygote for a mutant CYP2C19 allele and therefore lacks a functional CYP2C19 enzyme. The exposure of lansoprazole is up to 5-fold higher in PMs than in extensive metabolisers (EMs).

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Disodium hydrogen phosphate dehydrate
Gelatine capsules
Macrogol
Maize starch
Methacrylic acid-ethyl acrylate copolymer (1:1) 30 % dispersion
Polysorbate
Polyvinylpyrrolidone
Sodium lauryl sulphate
Sucrose
Sugar spheres
Talc
Titanium dioxide.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store in a dry place at or below 25 °C.
Keep the capsules in the original container until required for use.

6.5 Nature and contents of container
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.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE 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)

8. REGISTRATION NUMBER
A49/11.4.3/0229

9. DATE OF FIRST AUTHORISATION
24 May 2022

10. DATE OF REVISION OF THE TEXT
07 August 2024

PATIENT INFORMATION LEAFLET

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.
- Do 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 *Helicobacter pylori (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
Safety and efficacy in children has not yet been established.

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 e