LANCAP

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
LANCAP 15 mg capsules
LANCAP 30 mg capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
LANCAP 15 mg: each capsule contains lansoprazole 15 mg.
LANCAP 30 mg: each capsule contains lansoprazole 30 mg.

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)
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Capsules.
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 capsule are white.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- LANCAP 30 mg is indicated for the short-term treatment of gastric and duodenal ulcers and reflux oesophagitis
- LANCAP is indicated for *Helicobacter pylori*-positive duodenal ulcers in conjunction with appropriate antibiotics as part of an eradication programme.

4.2 Posology and method of administration
Posology
Gastric ulcer:
30 mg once a day for up to eight weeks.

Duodenal ulcer:
30 mg once a day for up to four weeks.
LANCAP is indicated for *Helicobacter pylori* positive ulcers, as part of an eradication program with appropriate antibiotics.

Oesophagitis due to gastro-oesophageal reflux:
30 mg once a day for four weeks. Depending on the endoscopic results, a repeat course of 4 weeks may be necessary.

Maintenance treatment for the prevention of gastro-oesophageal reflux:
15 mg once a day for a maximum period of one year.

Functional dyspepsia:
Adults: 15 - 30 mg once a day for 2 - 4 weeks.

Special populations
Elderly: no dose adjustment is necessary. However, 30 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
Safety and efficacy in children has not yet been established.

Method of administration
LANCAP should preferably be taken before a meal.

Missed dose:
Medical practitioners should advise patients who forget to take LANCAP 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
LANCAP is contraindicated in:
- hypersensitivity to lansoprazole or to any of the ingredients of LANCAP
- pregnancy and lactation (see section 4.6)
- severe liver impairment
- LANCAP is contraindicated with atazanavir or nelfinavir, as it substantially reduces exposure to the human immunodeficiency virus (HIV) protease inhibitor (see section 4.5).

4.4 Special warnings and precautions for use
Diagnosis of reflux oesophagitis:
Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Exclusion of malignant ulcers:
Treatment with LANCAP 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.

Effect of prolonged use:
Daily treatment with acid-suppressing medicines such as LANCAP 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. Rare reports of cyanocobalamin deficiency occurring with acid-suppressing therapy have been reported. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed.

Proton pump inhibitors such as LANCAP 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, has also been reported with proton pump inhibitors such as LANCAP treatment. For the suggestion that proton pump inhibitors such as LANCAP can cause calcium malabsorption (see section 4.8).

Subacute cutaneous lupus erythematosus (SCLE):
Proton pump inhibitors such as LANCAP are associated with very infrequent 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. SCLE after previous treatment with a proton pump inhibitor such as LANCAP may increase the risk of SCLE with other proton pump inhibitors.

Increased risk of *Clostridium difficile* associated diarrhoea:
LANCAP may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD). A diagnosis of CDAD should be considered for patients taking LANCAP who develop diarrhoea that does not stop. Patients should use the lowest dose and shortest duration of LANCAP therapy appropriate to the condition being treated.

Bone fracture:
LANCAP 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 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:
Severe hypomagnesaemia has been reported in patients treated with LANCAP for at least 3 months to one year. Hypomagnesaemia also produces impaired parathyroid hormone secretion which may lead to hypocalcaemia. Most patients had concomitant hypocalcaemia 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. For patients expected to be on prolonged treatment or who take LANCAP 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 (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 alone, but in extreme alkalosis or an impaired K^+ -recycling system, LANCAP may cause hypokalaemia unrelated to hypomagnesaemia.

Concomitant use with methotrexate:
Concomitant use of LANCAP 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 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.
Decreased gastric acidity increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with LANCAP may lead to an increased risk of gastrointestinal infections such as *Salmonella*, and *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 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, is possibly porphyrinogenic and should be used only when no safer alternative is available, and precautions should be considered in all patients.

Acute interstitial nephritis:
Acute interstitial nephritis has been observed in patients taking proton pump inhibitors (PPIs) including LANCAP. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction and is associated with damage to the tubulointerstitium, leading to acute kidney injury. Patients may present with varying signs and symptoms from symptomatic hypersensitivity reactions to non-specific symptoms of decreased renal function (e.g. malaise, nausea, anorexia). In reported case series, some patients were diagnosed on biopsy and in the absence of extra-renal manifestations (e.g. fever, rash or arthralgia). Interstitial nephritis may lead to renal failure. Discontinue LANCAP if acute interstitial nephritis develops (see section 4.8).

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 regularly performed in these patients.

Colitis:
Colitis has occurred in patients taking lansoprazole as contained in LANCAP. 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 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:
Patients with rare hereditary problems such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take LANCAP.

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

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

4.5 Interaction with other medicines and other forms of interaction
Effects of LANCAP on other medicines
Medicines with pH dependant absorption:
LANCAP causes a profound and long-lasting inhibition of gastric acid secretion, therefore it is possible that LANCAP may interfere with the absorption of medicines where gastric pH is an important determinant of bioavailability (e.g. itraconazole, ketoconazole, posaconazole, ampicillin esters, iron salts, digoxin, atazanavir, dasatinib and erlotinib). If voriconazole is taken concomitantly with LANCAP the plasma concentration of both medicines may be increased.

HIV protease inhibitors:
It has been shown that co-administration of atazanavir with proton pump inhibitors such as LANCAP results in a substantial reduction in the bioavailability of atazanavir. Therefore, LANCAP 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, may result in subtherapeutic concentrations of ketoconazole and itraconazole and the combination should be avoided.

Methotrexate:
Concomitant administration of methotrexate (particularly in high doses) with LANCAP may elevate and prolong serum concentrations of methotrexate and/or its metabolite hydromethotrexate. However, no formal interaction studies of high dose methotrexate with PPIs such as LANCAP have been conducted (see section 4.4).

Digoxin:
The absorption of digoxin may be enhanced if taken with LANCAP, resulting in increased plasma concentrations. Plasma levels of digoxin should thus be monitored and if necessary, the dosage adjusted upon initiating and ending LANCAP treatment.

Warfarin:
The response to anticoagulants such as warfarin may be affected by any concomitant medicine. It is therefore good practice to monitor the patient with additional PT (prothrombin time)/INR (international normalised ratio) determinations when LANCAP is initiated, discontinued or taken irregularly, since a minor reduction in the concentration of warfarin may occur.

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

Theophylline:
LANCAP 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 is commenced or discontinued, to ensure clinically effective blood levels. Caution is thus advised when used in combination.

Tacrolimus:
Co-administration of LANCAP may cause an increase in tacrolimus plasma concentrations and result in a decreased clearance. Monitoring of tacrolimus plasma concentrations is advised when concomitant treatment with LANCAP is initiated or ended.

Medicines transported by P-glycoprotein
Lansoprazole, as in LANCAP, 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
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, can reduce the plasma concentrations of lansoprazole.

Others
Sucralfate/antacids:
Administration of LANCAP concomitantly with sucralfate delays absorption of the proton pump inhibitor and reduces bioavailability by approximately 17 %. Therefore, LANCAP should be taken at least 30 minutes prior to sucralfate.
The administration of antacids and LANCAP does not interfere with its effect.

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

Since LANCAP is a weak inducer of the cytochrome P450 system, the possibility exists for interactions with medicines which are metabolized via this system, such as warfarin, antipyrine, indomethacin, ibuprofen, or other nonsteroidal anti-inflammatory medicines (NSAIDs); oral contraceptives, phenytoin, propranolol, prednisone, diazepam or clarithromycin.

The decrease in gastric activity with LANCAP may give false positive results in diagnostic investigations for neuroendocrine tumours and treatment should be stopped before such investigations.

Treatment with LANCAP may cause false-negative results in the urea breath test for *Helicobacter pylori* infection. It is recommended that a urea breath test should not be performed for at least 2 weeks after stopping treatment with LANCAP.

LANCAP has been shown to have no clinically significant interaction with amoxicillin.

Concomitant administration of LANCAP with clopidogrel in healthy patients has no clinically important effect on exposure to the active metabolite of clopidogrel or clopidogrel-induced platelet inhibition. No dose adjustment of clopidogrel is necessary when administered with an approved dose of LANCAP.

4.6 Fertility, pregnancy and lactation
Pregnancy
Adequate and well-controlled studies in humans have not been done (see section 4.3).

Breastfeeding
It is not known whether lansoprazole is distributed into breast milk. However, lansoprazole or its metabolites are distributed into the milk of rats. Lansoprazole has been shown to cause tumourigenic effects in animals.

4.7 Effects on ability to drive and use machines
Caution is advised since LANCAP can influence the ability to drive and use machines (see section 4.8). Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

4.8 Undesirable effects
a. Tabulated list of adverse reactions

System Organ Class	Frequency	Side effects
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
	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
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
Gastrointestinal disorders	*Frequent*	Diarrhoea, dry mouth or throat, nausea, vomiting, constipation, abdominal pain, flatulence
	Less frequent	Abnormal stools, anorexia, bezoar, cardiospasm, 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
Gastrointestinal disorders continued	*Less frequent*	Thirst, tongue disorder, ulcerative colitis, ulcerative stomatitis, pancreatitis (sometimes fatal)
Hepatobiliary disorders	*Frequent*	Elevation in hepatic enzymes
	Less frequent	Hepatitis, jaundice, hyperbilirubinaemia
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 carcinoma, skin disorder, sweating, Stevens-Johnson syndrome or toxic-epidermal necrolysis, photosensitivity, petechiae, purpura
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
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, interstitial nephritis; in some patients, renal failure has been reported concomitantly (see section 4.4)
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
General disorders and administrative site conditions	*Frequent*	Fatigue
	Less frequent	Asthenia, carcinoma, chest pain, chills, fever, flu syndrome, halitosis, infection, 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, in humans are not known (although the acute toxicity is likely to be low) and, consequently, instructions for treatment cannot be given. 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.
See 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, 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 being 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 - 3,2 hours - 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.

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 15 mg capsules are available in white HDPE bottles closed with a polypropylene tamper-evident cap with mounted desiccant insert containing 7, 14, 28 or 30 capsules.
LANCAP 30 mg capsules are available in white HDPE bottles closed with a polypropylene tamper-evident cap with mounted desiccant insert containing 14, 28 or 30 capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special precautions.

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 NUMBERS
LANCAP 15 mg: A40/11.4.3/0247
LANCAP 30 mg: A40/11.4.3/0248

9. DATE OF FIRST AUTHORISATION
Date of registration: 02 March 2007

10. DATE OF REVISION OF THE TEXT
07 August 2024

NAMIBIA
LANCAP 15 mg: NS2 07/11.4.3/0098
LANCAP 30 mg: NS2 07/11.4.3/0099

PATIENT INFORMATION LEAFLET

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 healthcare 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 human immunodeficiency virus (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 B12 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 difficil*e associated diarrhoea (CDAD) (you may develop diarrhoea that does not stop). Contact your doctor or healthcare 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 gastrointestinal infections such as *Salmonella*, and *Campylobacter*, *Shigella* or *Clostridium difficile*
- if you suffer from stomach ulcers you may be at risk of *Helicobacter pylori (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 (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 establishd.

Other medicines and LANCAP
Always tell your healthcare 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 tuberculosis (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 healthcare 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 healthcare 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
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 (0,023 g) 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 healthcare 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 blood 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, earache, ringing of the ears
- flushing, dizziness and feeling lightheaded, migraine, fainting
- difficulty in breathing/tight chest, 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, 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 substance 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 dehydrate, gelatine capsules, macrogol, maize starch, methacrylic acid-ethyl acrylate copolymer (1:1) 30 % dispersion, 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.
Not all pack sizes may be marketed.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

LANCAP 15 mg kapsules
LANCAP 30 mg kapsules
Lansoprasool
LANCAP bevat suiker (sukrose) in die volgende hoeveelhede:
LANCAP 15 mg (16,55 mg en suikersfere 70,0 mg),
LANCAP 30 mg (33,10 mg en suikersfere 140, 0 mg)

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om LANCAP te neem.
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- LANCAP is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Wat hierdie inligtingsblad bevat
1. Wat LANCAP is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u LANCAP neem
3. Hoe om LANCAP te neem
4. Moontlike newe-effekte
5. Hoe om LANCAP te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat LANCAP is en waarvoor dit gebruik word
- LANCAP word gebruik vir die korttermyn behandeling van gastriese (maag) en duodenale (dunderm) ulkusse en inflammasie van die esofagus, weens die refluks van maagsuur
- LANCAP word aangedui vir *Helicobacter pylori*-positiewe duodenale (dunderm) ulkusse in samewerking met gepaste antibiotika, as deel van 'n uitwissingsprogram.

2. Wat u nodig het om te weet, voordat u LANCAP neem
Moet nie LANCAP neem:
- indien u hipersensitief (allergies) is vir lansoprasool, of enige van die ander bestanddele van LANCAP nie (sien afdeling 6)
- indien u swanger is of u baba borsvoed nie
- indien u erge lewerbelemmering het nie
- indien u tans menslike immuniteitsgebrekvirus (MIV) medisyne, soos atasanavir of nelfinavir neem nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met LANCAP:
U dokter mag 'n bykomende ondersoek, wat 'n endoskopie genoem word, uitvoer (of reeds uitgevoer het), om sodoende u toestand te diagnoseer en/of kwaadaardige siektes uit te skakel.
- indien u simptome soos onopsetlike gewigsverlies, herhalende braking, problematiese sluk, bloed in braaksel, donker, klewerige fekes ervaar, of indien u 'n maagseer vermoed, vertel u dokter, aangesien LANCAP die simptome van kwaadaardige ulkusse mag verberg
- indien u LANCAP langdurig gebruik (bv. langer as 3 jaar), aangesien dit mag lei tot 'n vitamien B12 tekort
- soos met alle suurverlagende medisyne, mag LANCAP die absorpsie van sekere medisyne soos vitamien C en kalsium, beïnvloed
- indien u 'n veluitslag ontwikkel, veral op gedeeltes wat aan die son blootgestel is, vertel u dokter so gou as moontlik, aangesien dit nodig mag wees om u behandeling met LANCAP te staak. Onthou ook om enige ander newe-effekte, soos pyn in u gewrigte te noem
- LANCAP mag verband hou met 'n toenemende risiko vir *Clostridium difficile* geassosieerde diarree (CDGD) (u mag diarree ontwikkel wat nie ophou nie). Kontak u dokter of gesondheidsorgverskaffer so gou as moontlik
- LANCAP mag u risiko vir osteoporoseverwante beenfrakture van die heup, gewrig of ruggraat, verhoog. Lig u dokter in, indien u osteoporose het
- indien u ingelig is dat u lae magnesiumvlakke in u bloed het, of indien u uitputting, tetanie (pynlike sametrekkings van die kakebeen en nekspiere), delirium, konvulsies, duiseligheid en 'n verandering in normale hartklop ervaar, of indien u medisyne soos digoksien of diuretika (watertablette) neem, vertel u dokter, aangesien LANCAP u magnesiumvlakke verder mag verlaag
- indien u metotreksaat neem (gebruik vir die behandeling van kanker en leukemie), aangesien LANCAP die werking van hierdie medisyne mag aantas
- indien u LANCAP oor 'n lang tydperk neem, mag u 'n risiko toon vir gastrointestinale infeksies soos *Salmonella* en *Campylobacter*, *Shigella*, of *Clostridium difficile*
- indien u aan maagsere ly, mag u 'n risiko toon vir *Helicobacter pylori (H.pylori)* (bakteriële infeksie)
- LANCAP mag u lomerig maak en u konsentrasie inperk, wat vererger mag word deur alkoholverbruik
- indien u porfirie het, lig u dokter in, voordat u LANCAP neem
- LANCAP mag die niere beïnvloed (interstisiële nefritis). Lig u dokter in, indien u lae rugpyn, of enige pyn ervaar, terwyl u urineer
- indien u LANCAP op 'n langtermyn basis neem (langer as 1 jaar), sal u dokter u heelwaarskynlik onder gereelde toesig plaas. U moet enige nuwe en uitsonderlike simptome en omstandighede met u dokter deel, wanneer u die dokter besoek
- LANCAP mag kolitis veroorsaak (inflammasie van die kolon). Indien u erge en/of volhardende diarree ervaar, moet u die gebruik van LANCAP staak
- indien u 'n spesifieke bloedtoets (Chromogranien A) beplan, vertel u dokter voordat u LANCAP neem, aangesien dit met die toetsresultate mag inmeng
- indien daar 'n afname in u volume urine is, of
- indien u bloed in u urine het.

Kinders
Veiligheid en doeltreffendheid in kinders is nog nie bewys nie.

Ander medisyne en LANCAP
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende of tradisionele medisyne in).

LANCAP mag die werking van die volgende medisyne beïnvloed:
- LANCAP mag die absorpsie van die volgende medisyne beïnvloed: itrakonasool, ketokonasool, posakonasool, vorikonasool (om swaminfeksies te behandel), ampisillien (antibiotikum), ysteraanvullings, atazanavir, nelfinavir (om MIV te behandel), dasatinib, erlotinib (om kanker te behandel)
- metotreksaat (om kanker te behandel)
- digoksien (om hartprobleme te behandel)
- warfarien (om bloedklonte te voorkom)
- teofillien (om 'n toe bors te behandel)
- takrolimus werking (om oorplantingsverwerping te voorkom), mag versterk word deur LANCAP.

Medisyne wat die werking van LANCAP mag beïnvloed
- indien u fluvoksamien neem (gebruik om depressie te behandel), mag die effek van LANCAP versterk word
- Johanneskruid (om depressie te behandel) en rifampisien (om tuberkulose (TB) te behandel)
- sukralfaat (om ulkusse te behandel), of teensuurmiddels (om sooibrand te behandel)
- antipirien, indometasien, ibuprofen, of ander niesteroïedale anti-inflammatoriese middels (NSAIM) – (medisyne wat gebruik word om pyn te behandel)
- mondelikse voorbehoedmiddels
- fenitoïen (om epilepsie te behandel)
- propranolol (om hoë bloeddruk te behandel)
- prednisoon (om allergiese reaksies te behandel)
- diasepam (om spiere te verslap, of angstigheid te behandel)
- klaritromisien ('n tipe antibiotikum)

LANCAP mag sekere diagnostiese toetse vir sekere hormonale en senuweestelselgewasse, asook die ureumasemtoets vir bakteriële infeksies (*Helicobacter pylori*), beïnvloed.

LANCAP saam met kos en drinkgoed
Indien u LANCAP binne 30 minute van voedselinname neem, mag dit lei tot laer lansoprasool plasmavlakke. U moet dus LANCAP voor maaltye, verkieslik in die oggend, neem.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat u hierdie medisyne neem.

U moet nie LANCAP neem terwyl u swanger is of u baba borsvoed nie (sien Moet nie LANCAP neem).
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u gesondheidsorgverskaffer vir advies, voordat u LANCAP neem.

Bestuur en die hantering van masjiene
LANCAP mag u konsentrasie belemmer en lei tot lomerigheid. Indien u gelyktydig alkohol of ander sentrale senuweestelselonderdrukkers gebruik, mag die lomerigheid vererger word.
Moet nie motorvoertuie of masjinerie hanteer, of moontlik gevaarlike take uitvoer, waar 'n verlies van konsentrasie tot ongelukke mag lei, nie.
Dit is nie altyd moontlik om te voorspel, tot watter mate LANCAP met die daaglikse aktiwiteite van 'n pasiënt sal inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle weet hoe LANCAP hulle aantas nie.

LANCAP bevat suiker
Indien u dokter aangedui het, dat u 'n onverdraagsaamheid teenoor sekere suikers toon, kontak u dokter voordat u LANCAP neem.

LANCAP bevat natrium
LANCAP bevat minder as 1 mmol (0,023 g) sodium per kapsule, dit wil sê dit is wesenlik 'natriumvry'.

3. Hoe om LANCAP te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem LANCAP altyd presies soos deur u dokter of apteker aanbeveel is. U moet u dokter of apteker raadpleeg indien u onseker is.

Neem LANCAP voor 'n maaltyd, verkieslik in die oggend.

Die gewone dosis is een LANCAP 15 mg of een LANCAP 30 mg kapsule daagliks, afhangende van die toestand waarvoor u behandel word.

U dokter sal u vertel vir hoe lank u behandeling met LANCAP sal duur. Indien u onder die indruk is dat die effek van LANCAP té sterk, of té swak is, vertel u dokter of apteker.

Indien u meer LANCAP neem as wat u behoort
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om LANCAP te neem
Indien u 'n dosis oorslaan, neem dit so gou as wat u onthou. Indien dit egter amper tyd is vir u volgende dosis, hou aan om die volgende kapsule op die gewone tyd te neem. Moet nie 'n dubbeldosis neem, om op te maak vir die vergete individuele doserings nie.

Indien u die gebruik van LANCAP staak
Moet nie behandeling vroegtydig staak, omdat u beter begin voel nie. U toestand mag dalk nie volkome genees wees nie en mag hervat indien u nie die behandelingskursus voltooi nie.

4. Moontlike newe-effekte
LANCAP mag newe-effekte hê.
Nie alle newe-effekte wat vir LANCAP aangemeld is, word in hierdie inligtingsblad genoem nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar, terwyl u LANCAP neem, raadpleeg asseblief 'n gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van LANCAP en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik mag maak om te sluk of asem te haal
- uitslag of gejeuk
- koors
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, kon u 'n ernstige allergiese reaksie tenoor LANCAP ondervind het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- vergeling van die vel en oë, erge pyn in u bobuik, of u hele liggaam begin jeuk. Hierdie is tekens van ernstige lewerprobleme, insluitend geelsug en hepatitis
- LANCAP mag die hoeveelheid witbloedselle in u bloed verminder, wat so u vermoë om infeksies te beveg, mag verlaag.
Indien u enige infeksie, met simptome soos koors, of 'n ernstige agteruitgang in u algemene welstand, of 'n koors met simptome soos seer keel/mond, of blaasprobleme ervaar, moet u onmiddellik u dokter besoek
- borspyn, angina, veranderinge in die manier waarop u hart klop, byvoorbeeld, indien u opmerk dat dit vinniger, stadiger of onreëlmatig klop, moeisame asemhaling
- 'n volhardende, skubberige rooi vlek op die vel, met onreëlmatige buitelyne, wat somtyds 'n roof vorm of bloei (velkanker)
- Stevens-Johnson-sindroom (begin met griepsoortige simptome, gevolg deur 'n pynlike rooi area, wat vinnig versprei, velafskilfering sonder blasies, rou veloppervlaktes), of ander ernstige velversteurings
- erge nierprobleme: minder urine as wat normaal is vir u, swelling van die bene, enkels of voete, naarheid of uiterste moegheid, aanvalle of koma in erge gevalle
- indien u tekens van 'n beroerte ervaar, soos swakheid of gevoelloosheid in die gesig, arm of been, veral aan een kant van die liggaam; skielike verwarring, moeisame spraak of begrip; skielike sigprobleme in een of beide oë; skielike probleme om te loop; duiseligheid, balansverlies, erge of voortdurende hoofpyn met geen bekende oorsaak nie; bewussynsverlies of flouwording, met of sonder 'n aanval.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Algemene newe-effekte:
- hoofpyn, duiseligheid
- diarree, droë mond of keel, naarheid, braking (soms met bloed), hardlywigheid, winderigheid, maagpyn
- veranderinge in lewertoetsresultate (bv. verhoogde lewerensieme)
- gejeuk, skubagtige rooi, of pers ontsteekte vel, of uitslag
- uitputting.

Minder algemene newe-effekte:
- veranderinge in u bloedseltelling, of die hoeveelheid suiker in u bloed, wat u swak, moeg, bleek, of oor die algemeen ongesteld laat voel, anemie
- diabetes, goiter, (swelling van die nek, weens 'n vergroting van die skildklier), onderaktiewe skildklier
- vitamientekort, dehidrasie, pyn, styfheid of swelling in die gewrigte, uiterste dors, swelling van die hande of voete, nek of buikpyn, nek- of spierstyfheid, gewigstoename of -verlies, reuk- of smaaksteurnisse, spierswakheid, of krampe
- abnormale drome, gemoedsveranderinge, soos agitasie, vyandigheid, geheueverlies, angstigheid, luiheid, verwarring, 'n gevoel van selfonttrekking, depressie, buierigheid, hallusinasies (sien of hoor dinge wat nie bestaan nie), toename of afname in seksdrang, senuweeagtigheid, verdriet, onvermoë om te slaap
- aanval, dubbelvisie, verlamming aan die een kant van die liggaam, oormatige, abnormale liggaamsbewegings, spierstyfheid, afname in aanrakingsensitiwiteit, tintelende of branderige vel, rusteloosheid, vreemde gedagtes, slaperigheid, tremor, vertigo (die sensasie van 'n draaigevoel wanneer u stilstaan)
- abnormale of versteurde visie, gejeuk, waterige of rooi oë, droë oë, oogpyn, ligsensitiwiteit van die oë, versteurde visie en ander probleme met u sig, insluitend dubbelvisie.
- doofheid, oorprobleme, oorpyn, gelui in die ore
- blosvorming, duiseligheid en lighoofdige gevoel, migraine, floute
- moeisame asemhaling/toe bors, toename in gehoes, asemnood, neusbloeding, of hoes bloed, hik, seer of krapperige keel, of pynlike sluk, skerp borspyn, wat erger raak met asemhaling, loperige of verstopte neus, sinushoofpyn, abnormale geraas tydens asemhaling.
- bloeiende tandvleis, toename in eetlus of speeksel, mondseer, bloed in die stoelgang, abnormale smake, anoreksie, dors, tongversteuring, pyn in die binnekant van die mond, weens wit kolletjies op die tong, binnewange, tandvleis, verhemelte en/of mangels, die gevoel dat u opelyf benodig, selfs al het u dit alreeds gehad, inflammasie van die mond en lippe, pankreatitis (boonste abdominale pyn, wat na die rug uitstraal en vererger word, deur kos met 'n hoë vetinhoud te eet).
- aknee, haarverlies, droë vel, probleme met naels, gesweet, ligsensitiwiteit van die vel, afskilfering van die vel oor groot gedeeltes van die liggaam
- pynlike, geswelde, of stywe gewrigte, been- of gewrigsprobleme, beenkrampe, spier- of beenpyn, spierswakheid, frakture van die gewrig, heup of ruggraat, nekpyn of styfheid, bekkenpyn, hangende boonste ooglid, gewrigspyn, beenversteuring
- pyn of ongemak tydens urinering, bloed in die urine, rugpyn (nierpyn), uitermatige, of abnormaal groot volume urienproduksie, gereelde urinering of die drang om aanhoudend te urineer, urienweginfeksie
- 'n tipe nierprobleem (akute interstisiële nefritis). Sommige mense wie protonpompremmer (PPR) medisyne neem, insluitend LANCAP, mag 'n nierprobleem ontwikkel, wat interstisiële nefritis genoem word en op enige tydstip tydens die behandeling met PPR medisyne, mag voorkom. Raadpleeg u dokter onmiddellik, indien u 'n afname in die hoeveelheid wat u normaalweg urineer, of indien daar bloed in die urine voorkom
- abnormale menstruele siklusse (swaar, ligter, langer, of meer pynlik), borstevergroting of gevoeligheid by beide mans en vroue, impotensie, witterige of gelerige afskeiding, penisversteuring of ontsteekte vagina
- voel swak, borspyn, koue rillings, koors, griepsimptome, stink asem, infeksie, voel oor die algemeen ongesteld, swelling of waterterughouding
- verhoging in natrium, cholesterol en trigliseriede (vet) vlakke in die bloed.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- afname in magnesium-, kalsium-, en kaliumbloedvlakke, met simptome soos uitputting, onwillekeurige spiersametrekkings, disoriëntasie, konvulsies, duiseligheid, verhoogde harttempo
- indien u enige van hierdie simptome ervaar, raadpleeg u dokter onmiddellik. Lae magnesiumvlakke, mag ook lei to verlaagde kalium- of kalsiumvlakke in die bloed. U dokter mag besluit om gereelde bloedtoetse uit te voer en u magnesium-, kalsium- en kaliumvlakke te monitor.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem is nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word. Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van LANCAP in te win. U kan ook 'n epos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe om LANCAP te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar in 'n droë plek, teen of benede 25 ºC.
Hou die kapsules in die oorspronklike houer, totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat LANCAP bevat:
Die aktiewe bestanddeel is lansoprasool.
LANCAP 15 mg: die aktiewe bestanddeel in elke kapsule, is lansoprasool 15 mg.
LANCAP 30 mg: die aktiewe bestanddeel in elke kapsule, is lansoprasool 30 mg.

Die ander bestanddele is:
Dinatriumwaterstoffosfaatdehidraat, gelatienkapsules, metakielsuur-etielakrilaatkopolimeer (1:1) 30 % dispersie, makrogol, mieliestysel, natriumlourielsulfaat, polisorbaat, polivinielpirrolidoon, suikersfere, sukrose, talkum en titaandioksied.

Hoe LANCAP lyk en die verpakkingsinhoud
LANCAP 15 mg: kapsules gevul met wit tot ligbruin of effens pienk gekleurde korrels. Die liggaam van die harde gelatienkapsule is wit en die doppie is rooibruin gekleur.
LANCAP 30 mg: kapsules gevul met wit tot ligbruin, of effens pienk gekleurde korrels. Die liggaam en doppie van die harde gelatienkapsules is wit.

LANCAP 15 mg kapsules is beskikbaar in wit, plastiese bottels, met 'n peuterbestande deksel, wat 7, 14, 28 of 30 kapsules bevat.
LANCAP 30 mg kapsules is beskikbaar in wit, plastiese bottels, met 'n peuterbestande deksel, wat 14, 28 of 30 kapsules bevat.
Alle verpakkingsgroottes word nie noodwendig bemark nie.

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07 Augustus 2024

Registrasienommers
LANCAP 15 mg: A40/11.4.3/0247
LANCAP 30 mg: A40/11.4.3/0248

NAMIBIË
LANCAP 15 mg: NS2 07/11.4.3/0098
LANCAP 30 mg: NS2 07/11.4.3/0099