PROFESSIONAL INFORMATION FOR

LANSOLOC OTC CAPSULES

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

LANSOLOC OTC 15 mg capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each LANSOLOC OTC capsule contains 15 mg of lansoprazole

Contains sugar: Sucrose 18,00 mg

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Capsules.

White to off - white, enteric coated pellets in hard gelatine capsule shells, size “3”, with blue cap and white body.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LANSOLOC OTC is indicated in the short-term symptomatic relief of heartburn and hyperacidity at a maximum daily dose of 15 mg for a maximum period of 14 days.

4.2 Posology and method of administration

Posology

LANSOLOC should preferably be taken before a meal.

LANSOLOC OTC may be taken once daily at a maximum daily dose of 15 mg (one LANSOLOC OTC capsule) for a maximum treatment period of 14 days.

Patients should be advised to consult their doctor in the event of symptoms persisting, getting worse or continuing for 14 days (see **section 4.3**).

Special populations

Elderly:

No dose adjustment is necessary.

Renal impairment:

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

Paediatric population

Safety and efficacy in children have not been established.

Method of Administration

The recommended once daily dosage of LANSOLOC OTC should preferably be taken before a meal in the morning.

The capsules should be swallowed whole. Do not crush or chew.

4.3 Contraindications

LANSOLOC OTC is contraindicated in:

- Patients with hypersensitivity to lansoprazole or to any of the ingredients of LANSOLOC OTC listed in **section 6.1**.
- Pregnancy and lactation (see **section 4.6**).
- Patients with liver impairment.
- Conjunction with atazanavir or nelfinavir, due to a significant reduction in atazanavir or nelfinavir exposure (see **section 4.5**).

4.4 Special warnings and precautions for use

Safety and efficacy in children have not been established.

Treatment with LANSOLOC may alleviate the symptoms of malignant ulcers and can delay diagnosis. Therefore, the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded prior to treatment with LANSOLOC.

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Subacute cutaneous lupus erythematosus (SCLE):

Proton pump inhibitors including LANSOLOC OTC has been associated with cases of subacute cutaneous lupus erythematosus (SCLE). If lesions occur, particularly in sun–exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly. Treatment with LANSOLOC OTC may increase the risk of SCLE with other proton pump inhibitors.

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, malignancy should be excluded, as treatment with LANSOLOC OTC may

alleviate symptoms and delay diagnosis.

Therefore, the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded prior to treatment with LANSOLOC OTC, particularly in patients of middle age or older, who have new or recently changed dyspeptic symptoms.

LANSOLOC OTC is not indicated for mild gastrointestinal complaints, such as nervous dyspepsia.

Hypomagnesaemia

In patients treated with LANSOLOC OTC for three months or more severe hypomagnesaemia has been reported. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular dysrhythmia can occur, but they may begin insidiously and be overlooked. Discontinuation of LANSOLOC OTC and magnesium replacement will improve hypomagnesaemia in most affected patients.

For patients expected to be on prolonged treatment or who take LANSOLOC OTC with digoxin or medicines that may cause hypomagnesaemia (e.g., diuretics), healthcare professionals should consider measuring magnesium levels before starting LANSOLOC OTC treatment and periodically during treatment.

Bone fractures:

Proton pump inhibitors such as LANSOLOC OTC, especially if used in high doses and over extended periods of time (> 1 year), may increase the risk of hip, wrist and spine fracture, mainly in the elderly or where other recognised risk factors are present. Observational studies have suggested that proton pump inhibitors such as LANSOLOC OTC may increase the overall risk of fracture by 10 – 40 %. Patients who are at risk of

osteoporosis should have a sufficient intake of vitamin D and calcium and receive care according to current clinical guidelines.

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 LANSOLOC OTC may lead to an increased risk of gastrointestinal infections, such as with *Salmonella* and *Campylobacter* (see **section 4.8**).

Clostridium difficile-associated diarrhoea:

LANSOLOC OTC may also be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD), especially in hospitalised patients. This diagnosis should be considered for diarrhoea that does not improve.

Tubulointerstitial nephritis:

LANSOLOC OTC may increase the risk of subclinical acute or chronic interstitial nephritis which is associated with the use of Proton Pump Inhibitors (PPIs) which may lead to chronic renal inflammation and reduced renal function that may also progress to renal failure as it is not necessarily reversed when treatment is discontinued (see **section 4.8**).

Acute or chronic interstitial nephritis:

PPIs may trigger acute or chronic interstitial nephritis which is commonly associated with acute kidney injury (AKI). Hence, PPIs should be used carefully.

Patients on PPIs should be closely monitored for signs or symptoms of acute interstitial nephritis. These may range from symptomatic hypersensitivity reactions to non-specific symptoms of decreased renal function e.g. malaise, nausea and anorexia.

Sucrose

LANSOLOC OTC contains 0,018 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Since LANSOLOC OTC is metabolised through the cytochrome P450 system, specifically through the CYP3A and CYP2C19 isozymes, the possibility exists for interactions with other medicines that are metabolised via this system.

When administering LANSOLOC OTC with the CYP2C19 inhibitor fluvoxamine, a dose reduction should be considered, as plasma concentrations of LANSOLOC OTC increases up to 4-fold.

Enzyme inducers affecting CYP2C19 and CYP3A4 such as rifampicin and St John's wort (*Hypericum perforatum)* can significantly reduce the plasma concentrations of LANSOLOC OTC.

Studies have demonstrated that, in healthy subjects, LANSOLOC OTC does not have clinically significant interactions with other medicines metabolised by the cytochrome P450 system, such as phenazone, clarithromycin, diazepam, indomethacin, ibuprofen,

phenytoin, propranolol, or prednisone. These medicines are metabolised through various cytochrome P450 isozymes, including CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A.

When LANSOLOC OTC is co-administered with theophylline (CYP1A2, CYP3A), a minor increase (10 %) in theophylline clearance is observed. This interaction is unlikely to be of clinical concern given the small magnitude and direction of effect on theophylline clearance. Nonetheless, to ensure clinically effective blood levels, individual patients may require additional titration of their theophylline dosage when LANSOLOC OTC is started or stopped.

Concomitant use of proton pump inhibitors such as LANSOLOC OTC may elevate and prolong serum levels of methotrexate and/or its metabolites, possibly leading to methotrexate toxicities. It is recommended that in high-dose methotrexate administration, temporary withdrawal of LANSOLOC OTC should be considered.

Concomitant use of LANSOLOC OTC and tacrolimus increases the plasma concentrations of tacrolimus (a CYP3A and Pgp substrate). LANSOLOC OTC exposure increases the mean exposure of tacrolimus by up to 81 %. Monitoring of tacrolimus plasma concentrations is advised when concomitant treatment with LANSOLOC OTC is initiated or ended.

Increases in International Normalised Ratio (INR) and prothrombin time have been reported in patients who took proton pump inhibitors, including LANSOLOC OTC, and warfarin concomitantly. Increases in INR and prothrombin time may cause abnormal bleeding and result in death. Patients treated with LANSOLOC OTC and warfarin concomitantly may require monitoring for increases in INR and prothrombin time.

Caution should be exercised when oral contraceptives and carbamazepine are taken concomitantly with LANSOLOC OTC.

No clinically significant interaction was seen between LANSOLOC OTC and amoxicillin or non-steroidal anti-inflammatory drugs (NSAIDs).

Sucralfate delays absorption of proton pump inhibitors and reduces the bioavailability of single-dose lansoprazole 30 mg by 17 % when administered concomitantly. Therefore, LANSOLOC OTC should be taken at least 30 minutes before sucralfate.

Antacids may reduce the bioavailability of LANSOLOC OTC and should not be taken within 1 hour of LANSOLOC OTC.

LANSOLOC OTC causes a profound and long-lasting inhibition of gastric acid secretion. It is, therefore, theoretically possible that LANSOLOC OTC may interfere with the absorption of medicines where gastric pH is an important determinant of bioavailability (e.g. ketoconazole, itraconazole, voriconazole, ampicillin esters, iron salts, digoxin, and dasatinib). With voriconazole, the plasma concentration of both medicines may be increased.

Co-administration of LANSOLOC OTC and digoxin may lead to increased plasma levels of digoxin. Therefore the plasma levels of digoxin should be monitored and the dose of digoxin adjusted if necessary when initiating and ending LANSOLOC OTC treatment.

Since a significant reduction in atazanavir or nelfinavir exposure was reported when LANSOLOC OTC was administered concomitantly, LANSOLOC OTC should not be co-administered with atazanavir or nelfinavir (see **section 4.3**).

4.6 Fertility, pregnancy and lactation

LANSOLOC OTC is contraindicated during pregnancy and lactation (**section 4.3**).

Adequate and well-controlled studies in humans have not been done.

Breastfeeding

It is not known whether lansoprazole, as in LANSOLOC OTC, is distributed into breast milk. However, lansoprazole and its metabolites are distributed into the milk of rats and has been

shown to cause tumorigenic effects in animals.

Mothers on LANSOLOC OTC should not breastfeed their infants.

4.7 Effects on ability to drive and use machines

LANSOLOC OTC may lead to visual disturbances, drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants (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 visual disturbances or loss of concentration could lead to accidents.

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories, frequent, and frequency unknown.

MedDRA system organ Class	Frequency	Side effects
Infections and Infestations	Less Frequent	Candidiasis, infection, oral moniliasis, pneumonia, upper respiratory infection, urinary tract infection, otitis media.
	Frequency unknown	Clostridium difficile associated diarrhoea.
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Less frequent	Carcinoma, laryngeal neoplasia, skin carcinoma
Blood and lymphatic system disorders	Less frequent	Thrombocytopenia, anaemia, leukopenia, neutropenia, eosinophilia, haemolysis, lymphadenopathy, agranulocytosis, pancytopenia. Bruising, purpura, petechiae.
Immune system disorders	Less frequent	Allergic reaction.
	Frequency unknown	Bruising, purpura, petechiae.
Endocrine disorders	Less frequent	Diabetes mellitus, goitre, hypothyroidism, gynaecomastia, galactorrhoea

Metabolism and nutrition disorders	Less frequent	Anorexia, increased appetite, thirst, gout, dehydration, hyperglycaemia or hypoglycaemia, weight gain or loss. Hypomagnesaemia. Severe hypomagnesaemia may result in hypocalcaemia. Hypomagnesaemia may also be associated with hypokalaemia.
	Frequency unknown	Hyponatraemia, hypomagnesaemia.
Psychiatric disorders	Less frequent	Insomnia, somnolence, abnormal dreams, agitation, anxiety, apathy, depersonalisation, depression, emotional lability, hallucinations, aggravated hostility, increased or decreased libido, nervousness, neurosis, sleep disorders, thought-abnormalities.
Nervous system disorders	Frequent	Headache

	Less frequent	Cerebral infarction, migraine, amnesia, confusion, convulsion, hemiplegia, hyperkinesia, hyperaesthesia, paraesthesia, parosmia, taste loss, taste perversion, dizziness, tremor, somnolence, insomnia.
Eye disorders	Less frequent	Blurred vision, diplopia, abnormal vision, conjunctivitis, dry eyes, eye pain, photophobia, retinal degeneration, visual field defects.
Ear and labyrinth disorders	Less frequent	Vertigo, deafness, ear disorder, tinnitus.
Cardiac disorders	Less frequent	Angina, myocardial infarction, dysrhythmia, bradycardia, palpitations, tachycardia, syncope, oedema.
Vascular disorders	Less frequent	Hypertension, hypotension, shock (circulatory failure), vasodilation, peripheral oedema, cerebrovascular accident.
Respiratory, thoracic and mediastinal disorders	Less frequent	Asthma, bronchitis, increased cough, dyspnoea, epistaxis, haemoptysis, hiccups, pharyngitis, pleural disorder, respiratory disorder, upper respiratory inflammation, rhinitis, sinusitis, stridor.
Gastrointestinal disorders	Frequent	Diarrhoea, nausea, vomiting, constipation, abdominal pain.

	Less Frequent	Dry mouth, glossitis, ulcerative colitis, enlarged abdomen, halitosis, abnormal stools, bezoar, cardiospasm (oesophageal pain), colitis, dyspepsia, dysphagia, enteritis, eructation, oesophageal stenosis, oesophageal ulcer, oesophagitis, faecal discolouration, flatulence, gastric nodules or fundic gland polyps, gastritis, gastroenteritis, gastrointestinal anomalies, gastrointestinal disorders, gastrointestinal haemorrhage, gum haemorrhage, haematemesis, increased salivation, melaena, mouth ulceration, rectal disorders, rectal haemorrhage, stomatitis, tenesmus, tongue disorders, ulcerative stomatitis.
	Frequency unknown	Sore mouth or throat

Hepato-biliary disorders	Less frequent	Cholelithiasis, elevation of hepatic enzymes, jaundice [mostly in association with liver injury (an increase in up to twice the upper limit of the normal range of hepatic enzymes)], hyperbilirubinaemia, hepatitis.
	Frequency unknown	Hepatic failure, hepatic encephalopathy.
Skin and subcutaneous tissue disorders	Frequent	Skin rash, pruritus, urticaria.
	Less frequent	Alopecia, acne, contact dermatitis, dry skin, fixed eruption, hair disorders, maculopapular rash, nail disorders, skin disorders, sweating, Stevens- Johnson syndrome, or toxic epidermal necrolysis.
	Frequency unknown	Erythematous or bullous rashes, including Erythema multiforme, hair thinning, photosensitivity.
Musculoskeletal and connective tissue disorders	Less frequent	Arthralgia, myalgia, arthritis, bone disorders, joint disorders, leg cramps, musculoskeletal pain, myasthenia, synovitis, fractures of the hip, wrist or spine.

Renal and urinary disorders	Less frequent	Dysuria, kidney calculus, kidney pain, polyuria, urethral pain, urinary frequency, urinary urgency, urination impaired, interstitial nephritis (with possible progression to renal failure).
Reproductive system and breast disorders	Less frequent	Gynaecomastia, galactorrhoea, abnormal menses, breast enlargement, breast pain, breast tenderness, dysmenorrhoea, impotence, leucorrhoea, menorrhagia, menstrual disorders, penis disorders, testis disorders, vaginitis.
General disorders and administration site conditions	Less frequent	Asthenia, fever, back pain, chest pain, chills, flu syndrome, malaise, neck pain, neck rigidity, pain, pelvic pain.
	Frequency unknown	Fatigue.

Post-marketing:

MedDRA system organ Class	Frequency	Side effects
Renal and urinary disorders	Frequency Unknown	Interstitial nephritis (with possible progression to renal failure as it is not necessarily reversed when treatment is discontinued).

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

(See **section 4.4**)

In overdose, side effects can be precipitated and/or be of increased severity (see **section 4.8**).

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification

A 11.4.3 Antacids – Other

Pharmacotherapeutic group

Proton pump inhibitors

ATC code

A02BC03

Lansoprazole is a specific inhibitor of the gastric H+, K+-ATPase (proton pump) of the gastric parietal cell and thus inhibits the terminal step in acid production.

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

Since lansoprazole is unstable in an acidic environment, it is administered orally in the form of enteric-coated granules in capsules.

Following oral administration, lansoprazole is well absorbed with a resultant bioavailability of approximately 78 %. Statistical analyses of pharmacokinetic parameters revealed no significant differences between day 1 and day 7 after repeated doses in respect of Cmax, Tmax, AUC (area under the concentration-time curve), or half-life.

The bioavailability is decreased if lansoprazole is taken with food. As an acidic pH in the parietal cell acid canaliculi is required for activation, and since food stimulates acid production, lansoprazole should be taken about 30 minutes before meals.

Distribution

Peak serum concentrations are achieved approximately 1,5 hours following ingestion.

Lansoprazole is highly protein bound (97 %).

Metabolism:

Metabolism of lansoprazole occurs mainly in the liver. Lansoprazole is extensively metabolised via the hepatic cytochrome P450 system to the inactive, sulphated metabolites - sulphone, sulphide and 5-hydroxylansoprazole. These metabolites do not exhibit notable activity or toxicity. The plasma elimination half-life for lansoprazole is 1,4 to 1,5 hours. This does not change during treatment.

Elimination:

Lansoprazole is completely eliminated following oral administration. The main route of elimination is via the bile with 15 - 30 % of lansoprazole being excreted via the kidneys as the hydroxylated metabolite.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pellet Core:

Light magnesium carbonate

Povidone

Polysorbate 80

Hydroxypropylcellulose

Maize starch

Purified talc

Sucrose

Non pareil seeds

Seal coating:

Hydroxypropylmethylcellulose

Purified talc

Enteric coating:

Eudragit L 100

Purified talc

Titanium dioxide

Polysorbate 80

Polyethylene glycol PEG

Colloidal silicon dioxide

Capsule Shell Composition:

Titanium dioxide – Colour Index No. 77891

Brilliant Blue – Colour Index No. 42090

Erythosine – Colour Index No. 45430

Gelatin

SLS

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store at or below 25 °C.
- Store in a cool, dry place.
- Protect from light. Keep the blisters in the outer carton until required for use.

6.5 Nature and contents of container

Outer carton containing an aluminium foil blister strip of 7 capsules, packed in 7’s or 14’s.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 2,

Junxion Park

10 Elephant Lane,

Century City,

7441

8. REGISTRATION NUMBER(S)

37/11.4.3/0238

Botswana: S2 BOT1302380A

Namibia: NS2

06/11.4.3/0081

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 17 September 2004

Latest renewal: Not applicable.

10. DATE OF REVISION OF THE TEXT

29 September 2025