SCHEDULING STATUS:

S2

1. NAME OF THE MEDICINE

BURNLOC, 15 mg capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 15 mg Lansoprazole.

Contains sugar: Sucrose 0,1 g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsules.

No. 3, hard gelatine capsules, with opaque, yellow cap and body, containing white, or almost white, spherical microgranules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

BURNLOC 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

BURNLOC should preferably be taken before a meal.

Heartburn and hyperacidity:

One **BURNLOC** (15 mg) capsule daily for up to 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 population

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 capsule should be taken orally, preferably in the morning before meals (see section 5.2**).**

4.3 Contraindications

BURNLOC is contraindicated in:

- Patients with hypersensitivity to lansoprazole or to any of the ingredients of **BURNLOC** 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 **BURNLOC** 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 **BURNLOC**.

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Contains sucrose:
Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomaltase insufficiency should not take **BURNLOC.**

Contains mannitol:
May have a mild laxative effect.

Contains sodium (as in sodium laurilsulfate):
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

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 **BURNLOC** may lead to an increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*.

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 **BURNLOC** may alleviate symptoms and delay diagnosis.

Clostridium difficile-associated diarrhoea:
Proton pump inhibitor (PPI) therapy, including **BURNLOC**, may be associated with an increased risk of Clostridium difficile-associated diarrhoea (CDAD). This diagnosis should be considered for diarrhoea that does not improve.

Hypomagnesaemia:
Severe hypomagnesaemia has been reported in patients treated with PPIs like Lansoprazole, as in **BURNLOC**, for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness, and ventricular dysrhythmia can occur, but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the

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

Subacute cutaneous lupus erythematosus (SCLE):
Proton pump inhibitors have 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 **BURNLOC** 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 **BURNLOC** 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 **BURNLOC,** particularly in patients of middle age or older, who have new or recently changed dyspeptic symptoms.

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

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

Bone fractures:
Proton pump inhibitors including **BURNLOC** may increase the risk of hip, wrist and spine fracture, mainly in the elderly or where other recognised risk factors are present, especially if used in high doses and over extended periods of time (> 1 year). 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.

Tubulointerstitial nephritis:
BURNLOC may increase the risk of subclinical acute or chronic interstitial nephritis which is associated with the use of Proton Pump Inhibitors (PPIs). This 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.

4.5 Interactions with other medicines and other forms of interaction

- Since **BURNLOC** is metabolised through the cytochrome P450 system, specifically through the CYP3A and CYP2C19 isozymes, the possibility exists for interactions with medicines that are metabolised via this system.
- When administering **BURNLOC** with the CYP2C19 inhibitor fluvoxamine, a dose reduction should be considered, as plasma concentrations of **BURNLOC** increases up to 4-fold.
- *Enzyme inducers*: enzyme inducers affecting CYP2C19 and CYP3A4 such as rifampicin and St John's wort (*Hypericum perforatum)* can significantly reduce the plasma concentrations of **BURNLOC**.
- Studies have demonstrated that lansoprazole (as seen in **BURNLOC**) 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.
- *Theophylline*: co-administration of **BURNLOC** with theophylline may result in a minor increase in theophylline clearance. This interaction is unlikely to be of clinical concern considering the small magnitude and direction of effect on theophylline clearance. However, to ensure clinically effective blood levels, individual patients may require additional titration of their theophylline dosage when **BURNLOC** is started or stopped.
- Concomitant use of proton pump inhibitors such as **BURNLOC** 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 **BURNLOC** should be considered.

- Tacrolimus: concomitant use of **BURNLOC** and tacrolimus may increase the plasma concentrations of tacrolimus (a CYP3A and Pgp substrate). Lansoprazole, as in **BURNLOC**, exposure increases the exposure of tacrolimus. Monitoring of tacrolimus plasma concentrations is advised when concomitant treatment with **BURNLOC** is initiated or ended.
- Warfarin: monitoring of patients receiving concomitant warfarin is recommended, since a minor reduction in the concentration of warfarin may occur. Increases in International Normalised Ratio (INR) and prothrombin time have been reported in patients who took proton pump inhibitors and warfarin concomitantly. Increases in INR and prothrombin time may cause abnormal bleeding and result in death. Patients treated with **BURNLOC** and warfarin concomitantly may require monitoring for increases in INR and prothrombin time.
- *Oral contraceptives and carbamazepine*: caution should be exercised when oral contraceptives and carbamazepine are taken concomitantly with **BURNLOC**.
- No clinically significant interaction was seen between **BURNLOC** and amoxicillin or non-steroidal anti-inflammatory drugs (NSAIDs).
- *Methotrexate*: concomitant use of proton pump inhibitors such as **BURNLOC** 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 **BURNLOC** should be considered.
- *Sucralfate*: Sucralfate delays absorption of proton pump inhibitors and reduces the bioavailability of proton pump inhibitors when administered concomitantly. **BURNLOC** must be taken at least 30 minutes before sucralfate.
- *Antacids*: may reduce the bioavailability of **BURNLOC** and should not be taken within 1 hour of **BURNLOC**.
- Lansoprazole causes a profound and long-lasting inhibition of gastric acid secretion. It is, therefore, possible that **BURNLOC** 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.

- *Digoxin*: Co-administration of **BURNLOC** 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 **BURNLOC** treatment.
- A significant reduction in atazanavir or nelfinavir exposure was reported when lansoprazole was administered concomitantly, **BURNLOC** should not be co-administered with atazanavir or nelfinavir (see section 4.3).

4.6 Fertility, pregnancy and lactation

BURNLOC is contraindicated during pregnancy and lactation (see section 4.3).

Pregnancy

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

Breastfeeding

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

Mothers on **BURNLOC** should not breastfeed their infants.

4.7 Effects on ability to drive and use machines.

BURNLOC 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, less 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 (Haematological)	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	Less frequent	Asthma, bronchitis, increased cough, dyspnoea, epistaxis, haemoptysis,

mediastinal disorders		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, gynaecomastia, galactorrhoea, 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, haematemesis, increased salivation, melaena, mouth ulceration, rectal disorders, rectal haemorrhage, stomatitis, tenesmus, taste abnormalities, ulcerative stomatitis.
	Frequency unknown	Sore mouth or throat.
Hepato-biliary disorders	Less frequent	Elevation of hepatic enzymes, Cholelithiasis, 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.
	Frequent	Skin rash, pruritus, urticaria.

Skin and subcutaneous tissue disorders	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	Asthenia, arthralgia, myalgia, arthritis, bone disorders, joint disorders, leg cramps, musculoskeletal pain, myasthenia, synovitis, fractures of the hip, wrist or spine.
Renal and urinary disorders	Frequency Unknown	Interstitial nephritis (with possible progression to renal failure as it is not necessarily reversed when treatment is discontinued).
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.

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 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 SAHPRA website.

You may also report to Adcock Ingram Limited using the following email:
Adcock.AEReports@adcock.com

4.9 Overdose

(See **section 4.4**)

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 11.4.3 Medicines acting on the gastrointestinal tract.

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.

Distribution

Peak serum concentrations are achieved approximately 1 to 2 hours following ingestion. Lansoprazole is highly protein bound (97 %).

Metabolism

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

Elimination

The main route of elimination is via the bile with 15 to 30 % of lansoprazole being excreted via the kidneys as the hydroxylated metabolite.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each **BURNLOC** capsule contains the following excipients:

Gelatine;
Hypromellose;
Macrogol 6 000;
Mannitol;
Maize starch;
N-methylglucamine;
Polysorbate 80;
Purified water;
Quinolone yellow;
Sodium laurilsulfate;
Talc;
Titanium dioxide.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

- Store in a cool, dry place, at or below 25 ºC.
- Protect from light.
- Store in outer unit carton until required for use.

6.5 Nature and contents of container

The aluminium blister packs are available in pack sizes of 7 and 14 capsules. Each blister strip contains 7 capsules.

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

Adcock Ingram Limited
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1685
Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER

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