PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

BURNLOC, 15 mg capsules

Lansoprazole

Contains sugar: Sucrose 0,1 g

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

BURNLOC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **BURNLOC** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **BURNLOC** with any other person.
- Ask your pharmacist if you need information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. WHAT BURNLOC is and what it is used for

BURNLOC contains active substance Lansoprazole, which is a medicine known as proton pump inhibitors and reduces acid production in the stomach.

BURNLOC is used to treat conditions in which there is too much acid in the stomach.

BURNLOC is used for the short-term symptomatic relief of heartburn and acid indigestion at a maximum daily dose of 15 mg for a maximum period of 14 days.

2. What you need to know before you use BURNLOC

Do not take BURNLOC

- If you are hypersensitive (allergic) to lansoprazole or any of the other ingredients in **BURNLOC** listed in section 6.
- If you are breastfeeding or pregnant.
- If you suffer from liver impairment (poor liver function).
- If you are taking atazanavir or nelfinavir for Human Immunodeficiency Virus (HIV) infection.

Warnings and precautions

Special care should be taken with **BURNLOC:**

- If you develop a blistering rash on your skin, particularly in sun–exposed areas of the skin, and if you have pain in the joints, stop using **BURNLOC** and seek medical help immediately.
- If you are diabetic, as **BURNLOC** contains sugar.
- It is important to inform your doctor if you have recently experienced symptoms such as significant unintentional weight loss, recurrent vomiting, difficulty or pain with swallowing, vomiting blood, or passing of dark, tarry stools before you take

BURNLOC. When a stomach ulcer is suspected or present, cancer should be excluded, as treatment with **BURNLOC** may relieve symptoms and delay diagnosis.

- If you suffer from kidney problems.
- It may be associated with increased risk of *Clostridium difficile*- associated diarrhoea, gastrointestinal infections, and gastric glandular cysts.
- if you are on **BURNLOC** for more than three months, it is possible that the levels of magnesium in your blood may decrease. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium. Low levels of magnesium may develop symptoms such as tiredness, involuntary muscle contractions, disorientation, convulsions, dizziness, or increased heart rate. If you have any of these symptoms, please tell your doctor as soon as possible. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
- If you are suffering from gastric (stomach) ulcers or disease of the oesophagus (gullet).
- If you are experiencing mild pain or burning in the stomach, bloating or nausea after eating.
- If you are suffering from bone disease. Taking **BURNLOC** may increase hip, wrist and spine fracture especially if you are elderly.
- Please consult your doctor if you develop severe and/or persistent loose stools (diarrhoea) while taking **BURNLOC.** These symptoms may be due to inflammation of the large bowel (colon) and your doctor will have to decide whether you can safely continue to take **BURNLOC.**
- Please report to your doctor if you develop a combination of fever or chills, stomach pain or cramps, nausea, vomiting and loose stools with or without blood, since **BURNLOC** suppresses the secretion of stomach acid and you may therefore be more prone to develop infections involving the stomach and gut (see section 4).

Children and adolescents

Do not give **BURNLOC** to your child, since it is not known whether **BURNLOC** is safe and effective in children.

Other medicines and BURNLOC

Always tell your health care provider if you are using any other medicine. (This includes all complementary or traditional medicine.)

Please discuss the use of the following medicines in combination with **BURNLOC** with your doctor or pharmacist:

- *Atazanavir* or *nelfinavir* to treat HIV infection (see What you need to know before you take **BURNLOC**).
- *Warfarin* (blood thinning medicine) when used together with **BURNLOC** may increase your risk of bleeding. You will have to go for blood tests to monitor your INR and/or prothrombin time.
- *Enzyme inducers:* reduce the plasma concentrations of **BURNLOC**.
- *Theophylline* (medicines used to relax muscles of the lungs), you may require a change in the theophylline dose when you start or stop taking **BURNLOC**.
- *Methotrexate* (medicine used to treat cancer diseases and used to suppress the immune system).
- *Fluvoxamine*, an anti-depressant.
- *Rifampicin*, used for the treatment of tuberculosis (TB).
- *St. John's wort* (Hypericum perforatum), a herbal remedy used for mild depression.
- *Tacrolimus* (immunosuppressive medicine): concomitant use of **BURNLOC** and tacrolimus may increase the plasma concentrations of tacrolimus.
- *Oral contraceptives and carbamazepine*: caution should be exercised when oral contraceptives "(the pill)" and carbamazepine (used for epilepsy) are taken concomitantly with **BURNLOC**.

- *Sucralfate* (medicine used to treat and prevent ulcers in the intestines): **BURNLOC** must be taken at least 30 minutes before sucralfate.
- *Antacids* (medicine that neutralises acid in the stomach) should not be taken within 1 hour of taking **BURNLOC,** as they may reduce the bioavailability of **BURNLOC**.
- **BURNLOC** may possibly interfere with absorption of medicines where gastric pH is an important determinant of bioavailability (e.g. ketoconazole, itraconazole, voriconazole (antifungal medication), ampicillin esters (antibacterials), iron salts, digoxin (medicine used to treat various heart conditions) and dasatinib (medicine for cancer treatment).

BURNLOC with food and drink and alcohol

BURNLOC should be taken before eating.

Pregnancy and breastfeeding and fertility

Always tell your health care professional if you are taking any other medicine.

Do not take **BURNLOC** if you are pregnant or breastfeeding your baby.

If you are taking **BURNLOC**, you should not breastfeed your baby.

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 health care provider for advice before taking **BURNLOC.**

Driving and using machines

BURNLOC may lead to vision disturbances, drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other medicines.

When you start treatment with **BURNLOC**, you should take care while operating vehicles or machinery or performing potentially hazardous tasks where visual disturbances or concentration could lead to accidents.

BURNLOC contains sucrose

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

BURNLOC contains sucrose which may influence the control of your blood sugar if you have diabetes mellitus.

BURNLOC contains mannitol

Mannitol may have a mild laxative effect.

BURNLOC 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’.

3. How to take BURNLOC

Always take **BURNLOC** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

One **BURNLOC** capsule should be taken daily orally in the morning before food for up to 14 days.

Do not chew.

You should consult your doctor if the symptoms continue or worsen for more than 14 days.

Remember to take your medicine.

If you take more BURNLOC than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BURNLOC

Always take **BURNLOC** as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one capsule once daily. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BURNLOC capsules can have side effects.

Not all side effects reported for **BURNLOC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BURNLOC**, please consult your health care professional for advice.

If any of the following happens, stop taking **BURNLOC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the lips, tongue, or face, skin rash with hives and/or itching, difficult breathing, and constriction of the throat, since any combination of these symptoms may be due to an allergic reaction,
- Fainting spells,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BURNLOC**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- Nausea (feeling an urge to vomit.),
- Diarrhoea,
- Vomiting,
- Urticaria (Hives),
- Constipation,
- Abdominal cramps or stomach pains,
- Skin rash,
- Itchy skin.

Less frequent side effects:

- Fungal infection or thrush,
- Pneumonia and upper respiratory infection,
- Painful urination, pain over the bladder area, frequent urination, discolouration of urine or blood in the urine,
- otitis media (inflammation of the middle ear),
- cancer of the skin, voicebox and epithelial tissue,
- blood disorders,
- Swelling of the thyroid gland (in front of the neck),
- Bruising, and appearance of purple, red or brown spots and patches on your skin,
- Diabetes mellitus,
- Interstitial nephritis (kidney disease causing the inside of the kidney to become inflamed) which may progress to renal failure as it is not necessarily reversed when treatment is stopped,
- Any abnormal growth on the skin or swelling of the lymph glands,

- Excessive thirst or hunger accompanied by frequent urination and frequent infections,
- Severe pain, swelling and redness of a joint, such as that of the big toe,
- Severe pain in the hip, wrist or spine,
- Feeling hungry, weak or shaky with trembling hands,
- Depersonalisation (feeling as if your thoughts and actions are not your own, feeling "unreal") or aggravated hostility,
- Abnormal movements (hyperkinesia),
- An abnormally acute sense of pain, heat, cold, or touch, tremor, or pins and needles,
- Abnormal sense of taste or smell,
- Eye pain or sensitivity of eyes to light,
- Red or teary eyes or eye discharge (caking of the eyelids),
- Ear pain with or without a discharge,
- Palpitations,
- High blood pressure,
- Swelling of the feet, ankles or hands,
- Nose bleeds,
- Ulcers inside the mouth or on the lips, or inflammation of the tongue,
- Painful or difficult swallowing,
- Inability to pass stools,
- All other skin rashes, including a rash over areas exposed to the sun,
- Painful, swollen joints,
- Vaginal discharge or itching, penile discharge or itching, or testicular pain,
- Milky discharge from the breasts or breast enlargement in men,
- Loss of appetite or increased appetite,
- Thirst,
- Weight gain or loss,

- Sleeplessness, sleepiness, abnormal dreams, agitation, anxiety, listlessness, or depression,
- Struggling to control your emotions, increased or decreased libido, nervousness, sleep disorder or abnormal thinking,
- Dizziness,
- Dry eyes,
- A sensation of motion when you are sitting or standing still or ringing in the ears,
- Feeling faint or dizzy after standing up or flushing (red discolouration of the skin),
- Hiccups,
- Sore throat, runny or blocked nose or pain over the sinuses,
- Dry mouth, bad breath, flatulence (gas) or belching/burping, bloating of the stomach, indigestion, increased salivation (more spit than usual), or feeling as if you constantly need to pass stools, even though your bowels are already empty,
- Acne, hair loss, dry skin, nail or hair disorders, or increased sweating,
- Muscle pain or cramps, or bone pain,
- Abnormal menstruation, breast pain or tenderness, painful menstruation, or impotence,
- Unusual tiredness or weakness, back or neck pain, flu-like symptoms, feeling unwell, or pain in the pelvic area.

Frequency unknown:

- Tiredness, confusion, involuntary contraction of muscles, dizziness, convulsions and abnormal heart rhythm, since these may be due to low magnesium levels (see **Take special care with BURNLOC**),
- diarrhoea caused by the bacteria Clostridium difficile,
- bruising, and appearance of purple, red or brown spots and patches on your skin,
- sore mouth or throat,

- liver failure and hepatic encephalopathy (loss of brain function due to chronic liver disease),
- low levels of sodium and magnesium in the blood,
- redness and blistering of the skin,
- hair thinning and sensitivity to light,
- Interstitial nephritis (liver disease).

If any of the following happens, stop using **BURNLOC** and tell your doctor or pharmacist:

- Hypersensitivity reactions, non-specific symptoms of decreased kidney function such as a general sense of being unwell, nausea, eating disorder, etc. All these symptoms may be indicative of inflammation of the kidneys which possibly may lead to kidney failure.
- if you are on **BURNLOC** for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, or increased heart rate. If you get any of these symptoms, please tell 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.

These are the side effects of **BURNLOC**.

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 (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **BURNLOC**.

You may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. How to store BURNLOC

- Store all medicines out of reach of children.
- Store in a cool, dry place, at or below 25 ºC.
- Protect from light / moisture.
- Do not store in a bathroom.
- Store in the original package.
- 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.
- **KEEP OUT OF REACH OF CHILDREN.**

6. Contents of the pack and other information

What BURNLOC contains:

The active substance is Lansoprazole.

Each capsule contains Lansoprazole 15 mg.

The other ingredients are gelatine, quinolone yellow, titanium dioxide, hypromellose, macrogol 6 000, mannitol, maize starch, sucrose, N-methylglucamine, polysorbate 80, purified water, sodium laurilsulfate, talc.

What BURNLOC looks like and contents of the pack

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

BURNLOC is available in pack sizes of 7 and 14 capsules,

packaged in an aluminium blister. Each blister strip contains 7 capsules.

Blister strips are packed into a carton.

Not all pack sizes may be marketed.

Holder of certificate of Registration

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Access to the corresponding Professional Information

Not applicable.