**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S2**

**BURNLOC, 15 mg capsules**

**Lansoprazole**

**Contains sugar: Sucrose 100 mg**
**Mannitol 6,275 mg**

**Read all of 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.

2. What you need to know before you take **BURNLOC.**

3. How to take **BURNLOC**.

4. Possible side effects.

5. How to store **BURNLOC**.

6. Contents of the pack and other information.

**PATIENT INFORMATION LEAFLET**

## 1. WHAT BURNLOC is and what it is used for

**BURNLOC** contains the active substance lansoprazole, which is a medicine known as a proton pump inhibitor that 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 take 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.

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

**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 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 described or 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 orally preferably in the morning before food daily for up to 14 days.

Do not chew.

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

**If you take more BURNLOC 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 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.
- Store in the original package in order to protect from 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, quinoline yellow, titanium dioxide, Hypromellose (Methocel E5 Premium/Pharmacoat 606), macrogol 6 000, mannitol, maize starch, sucrose, N-methylglucamine, polysorbate 80, purified water, sodium laurilsulfate, talc, Methacrylic acid-ethyl acrylate copolymer.

**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 7,10 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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**REGISTRATION NUMBER**

A39/11.4.3/0116

**PASIËNT INLIGTINGSBILJET**

**SKEDULERINGSTATUS**

**S2**

**BURNLOC, 15 mg kapsules**

**Lansoprasool**

**Bevat suiker: Sukrose 100 mg**

**Mannitol 6,275 mg**

**Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u.**

**BURNLOC** is beskikbaar sonder 'n doktersvoorskrif vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds **BURNLOC** versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie **BURNLOC** met enige ander persoon deel nie.
- Raadpleeg u apteker indien u inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger of nie na 14 dae verbeter nie.

**Wat is in hierdie biljet**


1. Wat **BURNLOC** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **BURNLOC** neem.
3. Hoe om **BURNLOC** te neem.
4. Moontlike newe-effekte.
5. Hoe om **BURNLOC** te bêre.
6. Inhoud van die verpakking en ander inligting.


## 1. WAT BURNLOC is en waarvoor dit gebruik word

**BURNLOC** bevat die aktiewe bestanddeel lansoprasool, wat 'n medisyne is wat bekend staan as 'n protonpomp-inhibeerder, wat suurproduksie in die maag verminder.

**BURNLOC** word gebruik om toestande te behandel waar daar te veel suur in die maag is.

**BURNLOC** word gebruik vir die korttermyn simptomatiese verligting van sooibrand en slegte spysvertering as gevolg van maagsure, teen 'n maksimum daaglikse dosis van 15 mg vir 'n maksimum tydperk van 14 dae.

## 2. Wat u moet weet voordat u BURNLOC neem

### Moenie BURNLOC neem nie

- Indien u hipersensitief (allergies) is vir lansoprasool of enige van die ander bestanddele in **BURNLOC** gelys in afdeling 6.
- Indien u borsvoed of swanger is.
- Indien u aan lewerinkorting ly (swak lewerfunksie).
- Indien u atazanavir of nelfinavir neem vir menslike immuniteitsgebrekvirus (MIV) infeksie.

### Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet gedra word met **BURNLOC:**

- Indien u 'n blaserige uitslag op u vel ontwikkel, veral in sonblootgestelde areas van die vel, en indien u pyn in die gewrigte het, staak **BURNLOC** en soek onmiddellik mediese hulp.
- Indien u diabeet is, aangesien **BURNLOC** suiker bevat.
- Dit is belangrik om u dokter in kennis te stel indien u onlangs simptome ervaar het soos beduidende onbedoelde gewigsverlies, herhalende braking, probleme of pyn met sluk, braking van bloed of uitskeiding van donker, teeragtige stoelgang voordat u **BURNLOC** neem. Wanneer 'n maagseer vermoed word of teenwoordig is, moet kanker uitgeskakel word, aangesien behandeling met **BURNLOC** simptome kan verlig en diagnose kan vertraag.
- Indien u aan nierprobleme ly.

- Dit kan geassosieer word met verhoogde risiko van diarree geassosieer met *Clostridium difficile*, gastro-intestinale infeksies en maagkliersiste.
- Indien u  vir langer as drie maande op **BURNLOC** is, is dit moontlik dat die vlakke van magnesium in u bloed kan daal. U dokter kan besluit om gereelde bloedtoetse uit te voer om u vlakke van magnesium te monitor. Lae vlakke van magnesium kan lei tot simptome soos moegheid, onwillekeurige spiersametrekkings, disoriëntasie, stuiptrekkings, duiseligheid of verhoogde hartklop. Indien u enige van hierdie simptome ervaar, lig asseblief u dokter so gou as moontlik in. Lae vlakke van magnesium kan ook lei tot 'n verlaging in kalium- of kalsiumvlakke in die bloed.
- Indien u ly aan maagsere of siekte van die esofagus (slukderm).
- Indien u ligte pyn of branderigheid op die maag, opgeblasenheid of naarheid ervaar nadat u geëet het.
- Indien u aan beensiekte ly. Die neem van **BURNLOC** kan heup-, pols- en ruggraatfrakture verhoog, veral indien u bejaard is.
- Raadpleeg asseblief u dokter indien u ernstige en/of aanhoudende los stoelgange (diarree) ontwikkel terwyl u **BURNLOC** neem. Hierdie simptome kan voorkom as gevolg van inflammasie van die dikderm (kolon) en u dokter sal moet besluit of dit veilig is om voort te gaan om **BURNLOC** te neem.
- Lig asseblief u dokter in indien u 'n kombinasie van koors of kouekoors, maagpyn of krampe, naarheid, braking en los stoelgang met of sonder bloed ontwikkel, aangesien **BURNLOC** die afskeiding van maagsuur onderdruk en u dus meer geneig kan wees om infeksies te ontwikkel wat die maag en ingewande behels (sien afdeling 4).

**Kinders en adolessente**

Moenie **BURNLOC** aan u kind gee nie, aangesien dit nie bekend is of **BURNLOC** veilig en effektief is by kinders nie.

**Ander medisyne en BURNLOC**

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Bespreek asseblief die gebruik van die volgende medisyne in kombinasie met **BURNLOC** met u dokter of apteker:

- *Atazanavir* of *nelfinavir* om MIV-infeksie te behandel (sien **Wat u moet weet voordat u BURNLOC neem**).
- *Warfarien* (bloedverdunnende medisyne): wanneer dit saam met **BURNLOC** gebruik word, kan u risiko van bloeding verhoog. U sal vir bloedtoetse moet gaan om u INR en/of protrombientyd te monitor.
- *Ensieminduseerders:* verminder die plasmakonsentrasies van **BURNLOC.**
- *Teofillien* (medisyne wat gebruik word om die spiere van die longe te ontspan): u kan 'n verandering in die teofillien dosis benodig wanneer u begin of ophou om **BURNLOC** te neem.
- *Metotreksaat* (medisyne wat gebruik word om kankersiektes te behandel en gebruik word om die immuunstelsel te onderdruk).
- *Fluvoksamien*, 'n antidepressant.
- *Rifampisien*, wat gebruik word vir die behandeling van tuberkulose (TB).
- *“St. John’s Wort”* (*Hypericum perforatum*), 'n kruiemiddel wat gebruik word vir ligte depressie.
- *Takrolimus* (immuunonderdrukkende medisyne): gelyktydige gebruik van **BURNLOC** en takrolimus kan die plasmakonsentrasies van takrolimus verhoog.
- *Orale voorbehoedmiddels en karbamasepien*: wees versigtig wanneer orale voorbehoedmiddels (“die pil”) en karbamasepien (gebruik vir epilepsie) gelyktydig met **BURNLOC** geneem word.

- *Sukralfaat* (medisyne wat gebruik word om maagsere in die ingewande te behandel en te voorkom): **BURNLOC** moet ten minste 30 minute voor sukralfaat geneem word.
- *Teensuurmiddels* (medisyne wat suur in die maag neutraliseer) moet nie binne 1 uur na inname van **BURNLOC** geneem word nie, aangesien dit die biobeskikbaarheid van **BURNLOC** kan verminder.
- **BURNLOC** kan moontlik inmeng met die absorpsie van medisyne waar maag-pH 'n belangrike bepalende faktor van biobeskikbaarheid is (bv. ketokonasool, itrakonasool, vorikonasool (antifungus medikasie), ampisillien-esters (antibakteriese middels), ystersoute, digoksien (medisyne wat gebruik word om verskeie harttoestande te behandel) en dasatinib (medisyne vir kankerbehandeling).

**BURNLOC saam met kos en drank en alkohol**

**BURNLOC** moet voor etes geneem word.

**BURNLOC** kan lei tot visieversteurings, lomerigheid en verswakte konsentrasie, wat vererger kan word deur die gelyktydige inname van alkohol of ander medisyne.

**Swangerskap en borsvoeding en vrugbaarheid**

Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne neem.

Moenie **BURNLOC** neem indien u swanger is of u baba borsvoed nie.

Indien u **BURNLOC** neem, moet u nie u baba borsvoed nie.

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **BURNLOC neem.**

**Bestuur en gebruik van masjinerie**

**BURNLOC** kan lei tot visieversteurings, lomerigheid en verswakte konsentrasie, wat vererger kan word deur die gelyktydige inname van alkohol of ander medisyne.

Wanneer u met **BURNLOC** behandeling begin, moet u versigtig wees wanneer u voertuie

bestuur, masjinerie hanteer of potensieel gevaarlike take uitvoer waar versteurings in visie of konsentrasie tot ongelukke kan lei.

**BURNLOC bevat sukrose**

Indien u deur u dokter ingelig is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u **BURNLOC** neem.

**BURNLOC bevat natrium** (soos in natriumlourielsulfaat)

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per dosis-eenheid, dit wil sê is in wese 'natriumvry'.

## 3. Hoe om BURNLOC te neem

Neem altyd **BURNLOC** presies soos hierin beskryf of soos u dokter u opdrag gegee het.

Bevestig met u dokter of apteker indien u onseker is.

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Een **BURNLOC** kapsule moet mondelings geneem word, daagliks en verkieslik soggens voor kos geëet word, vir tot 14 dae.

Moenie kou nie.

U moet u dokter raadpleeg indien die simptome vir langer as 14 dae voortduur of vererger.

**Indien u meer BURNLOC neem as wat u moes**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

**Indien u vergeet om BURNLOC te neem**

Neem **altyd BURNLOC** soos aangedui. Indien u 'n dosis mis, neem dit sodra u onthou.

Indien u nie die oorgeslaande dosis onthou totdat die volgende dosis benodig is nie, verbeur die oorgeslaande dosis en gaan terug na u gereelde doseringskedule van een kapsule een keer per dag. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

## 4. Moontlike newe-effekte

**BURNLOC** kapsules kan newe-effekte hê.

Nie alle newe-effekte wat vir **BURNLOC** aangemeld is, word in hierdie biljet ingesluit nie.

Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u **BURNLOC** neem, raadpleeg asseblief u gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, staak **BURNLOC** en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Swelling van die lippe, tong of gesig, veluitslag met galbulte en/of jeukerigheid, moeilike asemhaling en vernouing van die keel, aangesien enige kombinasie van hierdie simptome te wyte kan wees aan 'n allergiese reaksie,
- floutes,
- veluitslag of jeukerigheid.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op **BURNLOC** gehad. U sal dalk dringende mediese hulp of hospitalisasie benodig.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte:

- Hoofpyn,
- Naarheid (voel 'n drang om te braak),
- Diarree
- Braking
- Urtikaria (galbulte),
- Hardlywigheid
- Abdominale krampe of maagpyne,
- Veluitslag,
- Jeukerige vel.

Minder gereelde newe-effekte:

- Swaminfeksie of sproei,
- Longontsteking en boonste respiratoriese infeksie,
- Pynlike urinering, pyn oor die blaasarea, gereelde urinering, verkleuring van urien of bloed in die urien,
- *Otitis media* (inflammasie van die middeloor),
- Kanker van die vel, stemkas en epiteelweefsel,
- Bloedafwykings,
- Swelling van die tiroïedklier (voor die nek),
- Kneusplekke, en voorkoms van pers, rooi of bruin kolle en areas op u vel,
- Diabetes mellitus,
- Interstisiële nefritis (niersiekte wat veroorsaak dat die binnekant van die nier ontsteek word) wat tot nierversaking kan vorder, aangesien dit nie noodwendig omgekeer word wanneer die behandeling gestaak word nie,
- Enige abnormale vergroeisel op die vel of swelling van die limfkliere,
- Oormatige dors of honger wat gepaard gaan met gereelde urinering en gereelde infeksies,
- Erge pyn, swelling en rooiheid van 'n gewrig, soos dié van die groottoon,
- Erge pyn in die heup, pols of ruggraat,
- Voel honger, swak of wankelrig met bewende hande,
- Depersonalisering (voel asof u gedagtes en optrede nie u eie is nie, voel "onwerklik") of verhoogde vyandigheid,
- Abnormale bewegings (hiperkinesie),
- 'n Abnormaal akute gevoel van pyn, hitte, koue of aanraking, bewing of naalde-en-spelde gevoel,
- Abnormale smaak- of reuksintuig,
- Oogpyn of sensitiwiteit van oë vir lig,

- Rooi of tranerige oë of oogafskeiding (koekerigheid op die ooglede),
- Oorpyn met of sonder afskeiding,
- Hartkloppings,
- Hoë bloeddruk,
- Swelling van die voete, enkels of hande,
- Neusbloeding,
- Sere in die mond of op die lippe, of inflammasie van die tong,
- Pynlike of moeilike sluk,
- Onvermoë om ontlasting uit te skei,
- Alle ander veluitslag, insluitend 'n uitslag oor gebiede wat aan die son blootgestel is,
- Pynlike, geswelde gewrigte,
- Vaginale afskeiding of jeukerigheid, penis-afskeiding of jeukerigheid, of testikulêre pyn,
- Melkerige afskeiding van die borste of borsvergroting by mans,
- Verlies aan eetlus of verhoogde eetlus,
- Dors,
- Gewigstoename of -verlies,
- Slapeloosheid, slaperigheid, abnormale drome, agitasie, angs, lusteloosheid of depressie,
- Sukkel om u emosies te beheer, verhoogde of verminderde libido, senuweeagtigheid, slaapversteuring of abnormale denke,
- Duiseligheid,
- Droë oë,
- 'n Sensasie van beweging indien u sit of stilstaan of ‘n gelui in die ore,
- Voel flou of duiselig nadat u opgestaan het, of blosing (rooi verkleuring van die vel),
- Hik,
- Seer keel, loopneus of geblokte neus of pyn oor die sinusse,
- Droë mond, onwelriekende asem, winderigheid (gas) of winde opbreek, opgeblasenheid van die maag, slegte spysvertering, verhoogde speekselvorming (meer spoeg as

gewoonlik), of voel asof u voortdurend ontlasting moet uitskei, al is u ingewande reeds leeg,

- Aknee, haarverlies, droë vel, nael- of haarafwykings, of verhoogde sweet,
- Spierpyn of krampe, of beenpyn,
- Abnormale menstruasie, borspyn of teerheid, pynlike menstruasie of impotensie,
- Ongewone moegheid of swakheid, rug- of nekpyn, griepagtige simptome, ongesteldheid of pyn in die bekkenarea.

Frekwensie onbekend:

- Moegheid, verwarring, onwillekeurige sametrekking van spiere, duiseligheid, stuiptrekkings en abnormale hartritme, aangesien dit te wyte kan wees aan lae magnesiumvlakke (sien **Wees veral versigtig met BURNLOC),**
- diarree veroorsaak deur die bakterie *Clostridium difficile,*
- kneusplekke, en voorkoms van pers, rooi of bruin kolle en areas op u vel,
- seer mond of keel,
- lewerversaking en lewer-enkefalopatie (verlies aan breinfunksie as gevolg van chroniese lewersiekte),
- lae vlakke van natrium en magnesium in die bloed,
- rooiheid en blaasvorming van die vel,
- verdunning van hare en sensitiwiteit vir lig,
- Interstisiële nefritis (lewersiekte).

Indien enige van die volgende gebeur, staak **BURNLOC** en lig u dokter of apteker in:

- Hipersensitiwiteitsreaksies, nie-spesifieke simptome van verlaagde nierfunksie soos 'n algemene gevoel van ongesteldheid, naarheid, eetversteuring, ens. Al hierdie simptome kan 'n aanduiding wees van inflammasie van die niere wat moontlik tot nierversaking kan lei.
- Indien u langer as drie maande op **BURNLOC** is, is dit moontlik dat die vlakke van magnesium in u bloed kan daal. Lae vlakke van magnesium kan gesien word as

moegheid, onwillekeurige spiersametrekkings, disoriëntasie, stuiptrekkings, duiseligheid of verhoogde hartklop. Indien u enige van hierdie simptome ervaar, lig asseblief u dokter dadelik in. Lae vlakke van magnesium kan ook lei tot 'n verlaging in kalium- of kalsiumvlakke in die bloed. U dokter kan besluit om gereelde bloedtoetse uit te voer om u vlakke van magnesium te monitor.

Hierdie is die newe-effekte van **BURNLOC.**

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

**Aanmelding van newe-effekte**

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat gevind kan word op SAHPRA se webwerf. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **BURNLOC** te verskaf.

U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-pos te gebruik: Adcock.AEReports@adcock.com

## 5. Hoe om BURNLOC te bêre

- Bêre alle medisyne buite bereik van kinders.
- Bêre op 'n koel, droë plek, teen of benede 25 ºC.
- Bêre in die oorspronklike verpakking om teen vogtigheid te beskerm.
- Moenie in 'n badkamer bêre nie.
- Bêre in die oorspronklike verpakking.
- Moenie gebruik ná die vervaldatum wat op die kartonhouer aangedui word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels weggooi nie.
- **HOU BUITE BEREIK VAN KINDERS.**

## 6. Inhoud van die verpakking en ander inligting

**Wat BURNLOC bevat:**

Die aktiewe bestanddeel is lansoprasool.

Elke kapsule bevat lansoprasool 15 mg.

Die ander bestanddele is gelatien, kinoliengeel, titaniumdioksied, Hipromellose (“Methocel E5 Premium/Pharmacoat 606”), makrogol 6 000, mannitol, mieliestysel, sukrose, N-metielglukamien, polisorbaat 80, gesuiwerde water, natriumlourielsulfaat, talk, metakrielsuur-etielakrilaat-kopolimeer.

**Hoe BURNLOC lyk en die inhoud van die verpakking**

Nr. 3, ondeursigtige geel dop en lyf, harde kapsules van gelatien gemaak, wat wit of amper wit, sferiese mikrogranules bevat.

**BURNLOC** is beskikbaar in verpakkingsgroottes van 7,10 en 14 kapsules, verpak in 'n aluminium-stulpstroke. Elke stulpstrook bevat 7 kapsules. Stulpstroke word in 'n kartonhouer verpak.

Nie alle verpakkingsgroottes mag dalk bemark word nie.

**Houer van Sertifikaat van Registrasie**

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**Hierdie biljet is mees onlangs hersien op**

26 Maart 2025

**PASIËNT INLIGTING BILJET**

**REGISTRASIENOMMER**

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