PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

BURNLOC (CAPSULE)

COMPOSITION:

Each capsule contains 15 mg Lansoprazole

Contains sugar: Sucrose 0.1 g

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.

CATEGORY AND CLASS:

A 11.4.3 Medicines acting on the gastrointestinal tract

PHARMACOLOGICAL ACTION:

Lansoprazole is an inhibitor of the gastric H^+ K^+ - ATPase (proton pump). Lansoprazole inhibits gastric acid secretion in a dose related manner irrespective of the source of stimulation. Gastric secretory functions recover gradually following discontinuation of the medicine. Lansoprazole has no effect on histamine, gastrin or cholinergic receptors.

Pharmacokinetics:

Following oral administration, lansoprazole is well absorbed with a resultant bioavailability of approximately 78 %. The bioavailability is decreased if lansoprazole is taken with food. Peak serum concentrations are achieved approximately 1 to 2 hours following ingestion. Lansoprazole is highly protein bound (97 %).

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.

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

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.

CONTRAINDICATIONS:

- Hypersensitivity to lansoprazole or to any of the ingredients.
- Pregnancy and lactation.
- Liver impairment.

WARNINGS AND SPECIAL PRECAUTIONS:

Safety and efficacy in children has 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**.

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

Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

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

Patients on PPI's 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, anorexia.

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

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.

Effects on ability to drive and use machines:

BURNLOC may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

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.

INTERACTIONS:

- Since **BURNLOC** is a weak inducer of the cytochrome P450 system, the possibility exists for interactions with medicines that are metabolised via this system.
- Monitoring of patients receiving concomitant warfarin is recommended, since a minor reduction in the concentration of warfarin may occur.

HUMAN REPRODUCTION:

Adequate and well-controlled studies in humans have not been done. It is not known whether lansoprazole is distributed into breast milk. However, lansoprazole or its metabolites are distributed into the milk of rats. Because lansoprazole has been shown to cause tumorigenic effects in animals, a decision should be made as to whether breastfeeding should be discontinued or **BURNLOC** withdrawn, taking into account the importance of lansoprazole to the mother.

DOSAGE AND DIRECTIONS FOR USE:

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 worst or continuing for 14 days (See **WARNINGS AND SPECIAL PRECAUTIONS**).

Elderly: No dose adjustment is necessary.

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

SIDE EFFECTS:

Haematological:

Less frequent: thrombocytopenia, anaemia, leucopenia, neutropenia, eosinophilia.

Cardiovascular:

Less frequent: oedema.

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Central nervous system:

Less frequent: headache, dizziness, somnolence, insomnia, tremor.

Gastrointestinal:

Frequent: diarrhoea, nausea, vomiting, constipation, abdominal pain.

Less frequent: dry mouth, glossitis, taste abnormalities, ulcerative colitis.

Endocrine disorders:

Less frequent: gynaecomastia, galactorrhoea.

Liver:

Less frequent: elevation in hepatic enzymes.

Musculoskeletal:

Less frequent: asthenia, arthralgia, myalgia.

Ocular:

Less frequent: blurred vision.

Skin:

Frequent: skin rash, pruritus, urticaria.

Less frequent: alopecia.

Other:

Less frequent: fever.

Infections and infestations:

Frequency unknown: Clostridium difficile-associated diarrhoea (See '**WARNINGS AND SPECIAL PRECAUTIONS').**

Renal and urinary disorders:

Frequency unknown: Interstitial nephritis (with possible progression to renal failure)*

*post-marketing experience

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

(See **'WARNINGS AND SPECIAL PRECAUTIONS'**)

Treatment is symptomatic and supportive.

IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store in a cool, dry place, at or below 25 ºC.

Protect from light.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Store in outer unit carton until required for use.

REGISTRATION NUMBER:

A39/11.4.3/0116

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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DATE OF PUBLICATION OF PROFESSIONAL INFORMATION:

Date of Registration: 07 July 2006

Date of Revision: 27 January 2021