"For Medical/ Pharmacy Professionals only"

Lansoprazole Delayed-Release Capsules USP

LPZ-30

Composition :

Each hard gelatin capsule contains:

Lansoprazole (as enteric coated pellets)	USP	30 mg
Excipients		q.s.

Approved colours used in empty capsule shells.

PHARMACOLOGICAL CLASSIFICATION:

Medicines acting on the gastrointestinal tract

PHARMACOLOGICALACTION:

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 secretary functions recover gradually following discontinuation of the medicine.

Lansoprazole has no effects on histamine, gastrine or cholinergic receptors

Pharmacokinetics:

Following oral administration, lansoprazole is well absorbed with a resultant bioavailability approximately 78%. The bioavailability is decreased if lansoprazole is taken with food, peak serum concentrations are achieved approximately 1-2 hours following ingestion.

Lansoprazole is highly protein bound (97%)

Lansoprazole is extensively metabolized via the hepatic cytochrome P450 system to the inactive sulphated metabolites, sulphone, sulphide and 5-hydroxylansoprazole, the half life of lansoprazole is 1.4 to 1.25 hours.

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

INDICATIONS:

Used in peptic ulcer and hyperacidity problems. Reflux of ulcerative oestophagitis, Zollinger-Ellinson Syndrome, NSAIDs-induced ulcers.

CONTRAINDICATION:

- Hypersensitivity to the lansoprazole.
- Pregnancy & Lactation
- Liver impairment

WARNING:

Safety and efficacy in children has not been established.

Treatment with lansoprazole may alleviate the symptoms of malignant ulcers and can delay diagnosis. Therefore the possibility of malignancy of gastric ulcer or malignant disease of esophagus should be excluded prior to treat with lansoprazole. The medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of the alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of the therapy, against taking charge of vehicles or machinery or performing potential hazardous task, where loss of concentration could lead to accidents.

INTERACTION:

Since lansoprazole is the slow inducer of cytochrome P-450 system, possibility exists for the interactions with drugs which are metabolized via the system.

Monitoring of patients receiving concomitant warfarin is recommended, since a minor reduction in the concentration of warfarin may occurs.

PREGNANCY AND LACTATION:

Adequate and well controlled studies in human have not been done

It is not known whether lansoprazole is distributed into Breast milk.

However, lansoprazole or its metabolites are distributed in milk of rats, because lansoprazole has been shown to cause tumerigenic effects in animals, a decision should be made as to whether nursing should be discontinued or the medicine withdrawn, taking the importance of lansoprazole to mother.

DOSAGE AND DIRECTIONS FOR USE:

Gastro Oesophageal Reflux Disease: Lansoprazole 30 mg once daily for 4 weeks. The majority of patients will be healed after the first course. For those patients not fully healed at this time, a further 4 weeks treatment at the same dosage should be given.

For long term management, a maintenance dose of Lansoprazole 15 mg or 30 mg once daily can be used, depend upon patient response.

Duodenal ulcer: Lansoprazole 30 mg once daily for 4 weeks.

For prevention of relapse, the recommended maintenance dose is Lansoprazole 15 mg once daily.

Acid-related dyspepsia: Intermittent courses, as required, of Lansoprazole 15 mg or 30 mg once daily for 2-4 weeks depending on the severity and persistence of symptoms. Patients who do not respond after 4 weeks, or who relapse shortly afterwards, should be investigated.

Benign gastric ulcer: Lansoprazole 30 mg once daily for 8 weeks.

Treatment of NSAID-associated benign gastric and duodenal ulcers and relief of symptoms: Lansoprazole 15 mg or 30 mg once daily for 4 or 8 weeks. Most patients will be healed after 4 weeks; for those patients not fully healed, a further 4 weeks treatment can be given.For patients at particular risk or with ulcers that may be difficult to heal, the higher dose and/or the longer treatment should be used.

Prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers and symptoms: Lansoprazole 15mg or 30mg once daily.

Hypersecretory conditions: The initial dose of Lansoprazole should be 60 mg once daily. The dosage should then be adjusted individually. Treatment should be continued for as long as clinically indicated.

For patients who require 120mg or more per day, the dose should be divided and administered twice daily.

Eradication of *H. pylori*: The following combinations have been shown to be effective when given for 7 days:

Lansoprazole 30 mg twice daily plus Clarithromycin 250-500 mg twice daily and Amoxycillin 1g twice daily, or Lansoprazole 30mg twice daily plus clarithromycin 250-500mg twice daily and Metronidazole 400 mg twice daily, or Lansoprazole 30mg twice daily plus amoxycillin 1g twice daily and metronidazole 400mg twice daily.

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

Elderly: Dose adjustment is not required in the elderly. The normal daily dosage should be given.

Children: The use of Lansoprazole is not recommended in children as clinical data are limited. Treatment of small children below one year of age should be avoided as available data have not shown beneficial effects in the treatment of gastro-oesophageal reflux disease.

Impaired Hepatic and Renal Function:

Lansoprazole is metabolized substantially by the liver. Clinical trials in patients with liver disease indicate that metabolism of Lansoprazole is prolonged when daily doses of 30 mg are administered to patients with severe hepatic impairment. It is therefore recommended that the daily dose for patients with severe liver disease is individually adjusted to 15mg or 30mg. These patients should be kept under regular supervision and a daily dosage of 30mg should not be exceeded.

There is no need to alter the dosage in patients with mild to moderate impairment of hepatic function or impaired renal function

SIDE EFFECTS AND SPEACIAL PRECAUTION:

In common with other anti-ulcer therapies, the possibility of malignancy should be excluded when gastric ulcer is suspected, as symptoms may be alleviated and diagnosis delayed. Similarly, the possibility of serious underlying disease such as malignancy should be excluded before treatment for dyspepsia commences, particularly in patients of middle age or older who have new or recently changed dyspeptic symptoms.

Lansoprazole should be used with caution in patients with severe hepatic dysfunction. These patients should be kept under regular supervision and a daily dosage of 30 mg should not be exceeded.

Decreased gastric acidity due to any means, including proton pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract.

Special warnings about the other ingredients:

Hypomagnesaemia:

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

For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics), health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognized risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Presentation:-

3x10 Capsules in a carton along with patient information leaflet.

Keep all the medicines out of reach of children

Store in a cool, dry & dark place.

Manufactured in India by :

LABORATE

PHARMACEUTICALS INDIA LTD.

51, Indl. Area, Paonta Sahib (HP)