

Lansazo[®]

Lansoprazole

Composition:

Lansoprazole.

Excipients: Maize starch, mannitol, hypromellose phthalate, sucrose, lactose, magnesium carbonate, povidone, carmellose calcium; hydroxypropyl cellulose, cetyl alcohol, sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate.

Properties:

Lansazo[®] (Lansoprazole) is a substituted benzimidazole. Chemically designated as 2-[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl sulphonyl benzimidazole.

Lansazo[®] is available in the form of enteric coated granules that are rapidly absorbed only after they leave the stomach, with an absolute bioavailability over 80%, with peak plasma concentrations achieved within approximately 1.5 hours, its plasma elimination half-life is 2 hours, and its duration of action is more than 24 hours. It is extensively metabolized in the liver into two inactive metabolites that undergo significant biliary excretion.

Mechanism of action:

Lansoprazole suppresses gastric acid secretion by the specific inhibition of the (H⁺, K⁺) ATPase enzyme system (acid pump) at the surface of gastric parietal cells, resulting in the blocking of the final step of acid production and so, the inhibition of both; basal and stimulated acid secretion regardless of the stimulus.

Indications:

Lansazo[®] is effective in treatment of acid-related disorders of the upper gastrointestinal tract, with the benefit of rapid symptomatic relief:

- Short-term treatment of active duodenal ulcer and active benign gastric ulcer.
- Maintenance of healed duodenal ulcer.
- Short-term treatment of symptomatic GERD.
- Acid-related dyspepsia.
- Short-term treatment of erosive esophagitis.
- Maintenance of healing of erosive esophagitis.
- *H. pylori* eradication in peptic ulcer disease with antibiotics.
- NSAID-associated duodenal or gastric ulcer.
- To reduce the risk of NSAID-associated gastric ulcer in patients with a history of gastric ulcer who require an NSAID.
- Long-term treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome.
- It is also effective in patients with benign peptic lesions, unresponsive to H₂-receptor antagonists.

Dosage and administration:

- For best results take Lansazo[®] capsules 30 minutes before food.
- *Active duodenal ulcer:* 15-30 mg once daily for 4 weeks.
- *Active benign gastric ulcer:* 30 mg once daily for up to 8 weeks.
- *Symptomatic GERD:* 15 mg once daily for up to 8 weeks.
- *Acid-related dyspepsia:* 15-30 mg daily in the morning for 2-4 weeks.

- *Erosive esophagitis:* 30 mg once daily for 8 weeks, a further 8 weeks treatment at the same dosage should be given when needed.
- *H. pylori eradication in peptic ulcer disease:* 30 mg once daily or 60 mg/day in 2 divided doses; in combination with antibiotics.
- *NSAID-associated duodenal or gastric ulcer (healing):* 15-30 mg once daily for 4 weeks, continued for further 4 weeks when needed.
- *NSAID-associated duodenal or gastric ulcer (prophylaxis):* 15-30 mg once daily for up to 12 weeks.
- *Pathological hypersecretory conditions including Zollinger-Ellison Syndrome:* The dosage should be individualized according to the desired patient response and for as long as needed. The usual starting dose is 60 mg once daily. Daily doses > 120 mg should be administered in divided doses.
- For maintenance therapy: 15 mg is given once daily to prevent relapse.

Contraindications:

Hypersensitivity to lansoprazole or any component of the product.

Drug interactions:

- Lansoprazole is a weak inducer of cytochrome P450 enzyme system; therefore, caution should be exercised when oral contraceptives and preparations such as phenytoin, theophylline, warfarin or other anticoagulants are taken concomitantly with lansoprazole.
- Lansoprazole may theoretically interfere with drug absorption that is determined by gastric pH, since it profoundly inhibits acid secretion (e.g., ketoconazole, ampicillin, iron salts and digoxin).
- Lansoprazole serum concentrations may be decreased if taken with food.
- Antacids may reduce the bioavailability of lansoprazole and should therefore be given one hour apart.

Warnings:

As with other antiulcerants, symptomatic response to treatment with lansoprazole does not preclude gastric malignancy.

Precautions:

- **Pregnancy: Category B;** use during pregnancy only if clearly needed.
- **Lactation:** It is not known whether lansoprazole is excreted in human breast milk, the physician should decide whether to discontinue nursing or to discontinue the drug according to the importance of the drug to the mother.
- Safety and efficacy have not been established in children <1 year of age.
- No dosage adjustment is necessary in elderly or renal impaired patients.
- Lansoprazole should be administered with caution to patients with severe hepatic disorder.
- For patients with difficulty in swallowing, capsules can be

opened and granules can be swallowed immediately, without crushing or chewing the granules.

Adverse reactions:

Generally, lansoprazole therapy is well tolerated in both short and long term treatment. Adverse reactions are generally transient and include diarrhea, abdominal pain, dyspepsia, nausea, vomiting, dry mouth, flatulence, constipation, headache, dizziness, fatigue, rash, urticaria and pruritus. Increase in liver function test values have been observed. Leukopenia and thrombocytopenia may occur.

Overdosage:

Lansoprazole is not removed from circulation by hemodialysis. Treatment should be symptomatic and supportive.

Information for the patient:

- For best results take Lansazo[®] capsules 30 minutes before food.
- Replace cap firmly after each use.
- Use the drug within one month from its opening date.
- If you have difficulty in swallowing the capsule, open it and swallow the content immediately without chewing or crushing the content.

Presentations:

Lansazo[®] 15 mg Capsules: Each capsule contains 15 mg Lansoprazole in packs of 14 capsules.
Lansazo[®] 30 mg Capsules: Each capsule contains 30 mg Lansoprazole in packs of 10, 14 and 28 capsules.

*Some presentations may not be available in certain countries.

(This is a medicament - Keep medicaments out of the reach of children)

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Last update: 4/2007



Hayat Pharmaceutical Industries Co. PLC
P.O. Box 1564
Amman 11118 Jordan