

LANZOTEC[®]

(Lansoprazole)

PROPERTIES:

Lansoprazole, the active ingredient in LANZOTEC[®], is a substituted benzimidazole proton pump inhibitor, chemically designated as 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]benzimidazole.

LANZOTEC[®] 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.

LANZOTEC[®] is available in the form of enteric coated pellets that are rapidly absorbed only after they leave the stomach, with an absolute bioavailability over 80%, a plasma half life of 15 hrs, and a duration of action of 24 hrs. It is extensively metabolized in the liver into two inactive metabolites that undergo significant biliary excretion.

INDICATIONS:

-Short-term treatment of active duodenal ulcers; maintenance treatment of healed duodenal ulcers; as part of a multidrug regimen for H. pylori eradication to reduce the risk of duodenal ulcer recurrence.

-Short-term treatment of active benign gastric ulcer; treatment of NSAID-associated gastric ulcer; to reduce the risk of NSAID-associated gastric ulcer in patients with a history of gastric ulcer who require an NSAID.

- Short-term treatment of symptomatic GERD; short-term treatment for all grades of erosive esophagitis; to maintain healing of erosive esophagitis; long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

DOSAGE AND ADMINISTRATION:

Indication	Recommended Dose	Frequency
Duodenal Ulcers Short-Term Treatment Maintenance of Healed	15 mg 15 mg	Once daily for 4 weeks Once daily
H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence Triple Therapy: LANZOTEC [®] Amoxicillin Clarithromycin Dual Therapy: LANZOTEC [®] Amoxicillin	30 mg 1 gram 500 mg 30 mg 1 gram	Twice daily (q12h) for 10 or 14 days Twice daily (q12h) for 10 or 14 days Twice daily (q12h) for 10 or 14 days Three daily (q8h) for 14 days Twice daily (q8h) for 14 days
Benign Gastric Ulcer Short-Term Treatment	30 mg	Once daily for up to 8 weeks
NSAID-associated Gastric Ulcer Healing Risk Reduction	30 mg 15 mg	Once daily for up to 8 weeks* Once daily for up to 12 weeks*
Gastroesophageal Reflux Disease (GERD) Short-Term Treatment of Symptomatic GERD Short-Term Treatment of Erosive Esophagitis	15 mg 30 mg	Once daily for up to 8 weeks Once daily for up to 8 weeks**
Pediatric (1 to 11 years of age) Short-Term Treatment of Symptomatic GERD and Short-Term Treatment of Erosive Esophagitis ≤ 30 kg > 30 kg (12 to 17 years of age) Short-Term Treatment of Symptomatic GERD Nonerosive GERD Erosive Esophagitis	15 mg 30 mg 15 mg 30 mg	Once daily for up to 12 weeks*** Once daily for up to 12 weeks*** Once daily for up to 8 weeks Once daily for up to 8 weeks
Maintenance of Healing of Erosive Esophagitis	15 mg	Once daily
Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome	60 mg	Once daily****

* Controlled studies didn't extend beyond indicated duration.

** For patients who do not heal with Lansoprazole for 8 weeks (5-10%), it may be helpful to give an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis, an additional 8 week course of Lansoprazole may be considered.

*** Lansoprazole dose was increased (up to 30 mg b.i.d) in some pediatric patients after 2 or more weeks of treatment if they remained symptomatic. For pediatric patients unable to swallow an intact capsule please see administration options.

**** Varies with individual patient. Recommended adult starting dose is 60 mg once daily. Doses should be adjusted to individual patients needs and should continue for as long as clinically indicated. Dosages up to 90 mg b.i.d. have been administered. Daily dose of greater than 120 mg should be administered in divided doses. Some patients with Zollinger-Ellison Syndrome have been treated continuously with Lansoprazole for more than 4 years.

Dosage adjustment in renal impairment: No dosage adjustment is needed
Dosing adjustment in hepatic impairment: dose reduction is necessary for severe hepatic impairment.

Administration

Oral: Administer before food. The intact pellets should not be chewed or crushed; however, several options are available for those patients unable to swallow capsules: Capsules may be opened and the pellets sprinkled on 1 tablespoon of applesauce, cottage cheese, yogurt, or strained pears. The

pellets should then be swallowed immediately.

Capsules may be opened and emptied into ~60 mL orange juice, apple juice, or tomato juice; mix and swallow immediately. Rinse the glass with additional juice and swallow to assure complete delivery of the dose.

Capsule pellets may be mixed with apple, cranberry, grape, orange, pineapple, prune, tomato and stored for up to 30 minutes.

Nasogastric tube administration: Capsules can be opened, the pellets mixed (not crushed) with 40 mL of apple juice and then injected through the NG tube into the stomach, then flush tube with additional apple juice.

•Do not use other liquids or foods.

CONTRAINDICATIONS:

Hypersensitivity to Lansoprazole or any component of the product.

DRUG INTERACTIONS:

Lansoprazole does not have clinically significant interactions with drugs metabolized by cyt. P450 system.

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).

ADVERSE REACTIONS:

Generally Lansoprazole therapy is well tolerated in both short and long-term treatments.

Some adverse reactions like diarrhea, nausea, abdominal pain, headache and skin rashes may occur.

PRECAUTIONS:

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

WARNINGS:

Pregnancy: Category B: use during pregnancy only if clearly needed.

Lactation: It is not known if Lansoprazole is excreted in human breast milk, the physician should decide to discontinue nursing or to discontinue the drug according to the importance of the drug to the mother.

Liver impairment: Consider dosage reduction in severe cases of hepatic impairment.

Elderly: For elderly patients, dosage and administration of lansoprazole need not be altered for a particular indication.

Dysphagia: For patients with difficulty in swallowing, capsule can be opened and pellets can be swallowed immediately, without crushing or chewing the pellets.

OVERDOSAGE:

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

DIRECTIONS:

- Take before meals.
- Replace cap firmly after each use.
- Use the drug within one month from opening date.
- If you have difficulty in swallowing the capsule, open it and swallow the content immediately without chewing or crushing the content.

PRESENTATION:

LANZOTEC[®] 15: Each capsule contains 15 mg Lansoprazole in packs of 15 and 30 capsules.

LANZOTEC[®] 30: Each capsule contains 30 mg Lansoprazole in packs of 15 and 30 capsules.

- A 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.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTRIES
UNION OF ARAB PHARMACISTS

Produced by:

JOSWE[®] medical

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