

# Lantanon

Lansoprazole 30 mg capsules

## DESCRIPTION

The active ingredient in lansoprazole is a substituted benzimidazole, a compound that inhibits gastric acid secretion.

## CLINICAL PHARMACOLOGY

### *Absorption*

Absorption of lansoprazole begins only after the granules leave the stomach. The absorption of lansoprazole is rapid, with absolute bioavailability over 80%. There is no significant food effect if the drug is given before meals.

### *Distribution*

Lansoprazole is 97% bound to plasma proteins.

### *Metabolism*

Lansoprazole is extensively metabolized in the liver. The plasma elimination half-life of lansoprazole does not reflect its duration of suppression of gastric acid secretion. Thus, the plasma elimination half-life is less than two hours, while the acid inhibitory effect lasts more than 24 hours.

### *Elimination*

Following single-dose oral administration of lansoprazole, virtually no unchanged lansoprazole is excreted in the urine. Approximately one-third of the administered radiation is excreted in the urine and two-thirds is recovered in the faeces. This implies a significant biliary excretion of the metabolites of lansoprazole.

## Special Populations

### *Renal Insufficiency*

AUC for free lansoprazole in plasma, however, was not related to the degree of renal impairment, and C<sub>max</sub> and T<sub>max</sub> were not different from subjects with healthy kidneys.

### *Hepatic Insufficiency*

An increase in mean AUC was observed at steady state in hepatically-impaired patients compared to healthy subjects. Dose reduction in patients with severe hepatic disease should be considered.

## MODE OF ACTION

Lansoprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the (H<sup>+</sup>, K<sup>+</sup>)-ATPase enzyme system at the secretory surface of the gastric parietal cell. Lansoprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production. This effect is dose-related and leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus.

## INDICATIONS AND USAGE

Lantanon capsules are indicated for:

### - **Short-Term Treatment of Active Duodenal Ulcer**

**Lantanon** is indicated for short-term treatment (up to 4 weeks) for healing and symptom relief of active duodenal ulcer.

### - **H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence**

*Triple Therapy:* **Lantanon** (lansoprazole) in combination with amoxicillin plus clarithromycin as triple therapy is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

*Dual Therapy:* **Lantanon** (Lansoprazole) in combination with amoxicillin as dual therapy is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected.

### - **Short-Term Treatment of Active Benign Gastric Ulcer**

**Lantanon** is indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of active benign gastric ulcer.

### - **Healing of NSAID-Associated Gastric Ulcer**

**Lantanon** is indicated for the treatment of NSAID-associated gastric ulcer in patients who continue NSAID use (up to 8 weeks).

- **Gastroesophageal Reflux Disease (GERD)**

*Short-Term Treatment of Symptomatic GERD*

**Lantanon** is indicated for the treatment of heartburn and other symptoms associated with GERD.

*Short-Term Treatment of Erosive Esophagitis*

**Lantanon** is indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of all grades of erosive esophagitis. For patients who do not heal with Lantanon for 8 weeks (5-10%), it may be helpful to give an additional 8 weeks of treatment.

- **Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome**

**Lantanon** is indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

## CONTRAINDICATIONS

**Lantanon** capsules are contraindicated in patients with known hypersensitivity to any component of the formulations.

## PRECAUTIONS AND ADMINISTRATION OPTIONS

- **Lantanon** should be taken before eating.

- *For patients who have difficulty swallowing capsules, **Lantanon** capsules can be opened and administered as follows:*

1. Open capsule and sprinkle intact granules into a small volume of either orange juice or tomato juice (60 ml).

2. Mix briefly.

3. Swallow immediately. The granules should not be crushed or chewed.

4. To insure complete delivery of the dose, the glass should be rinsed with two or more volumes of juice and the contents swallowed immediately.

- *For patients who have a nasogastric tube in place, **Lantanon** capsules can be administered as follows:*

1. Open capsule and mix intact granules into 40 mL of apple juice. **DO NOT USE OTHER LIQUIDS.**

2. Inject through the nasogastric tube into the stomach.

3. Flush with additional apple juice to clear the tube.

- Pregnancy:

Teratology studies have been performed in pregnant rats and pregnant rabbits and have revealed no evidence of impaired fertility or harm to the foetus due to lansoprazole. There are, however, no adequate or well-controlled studies in pregnant women.

## DRUG INTERACTION

- Studies have shown that lansoprazole does not have clinically significant interactions with other drugs metabolized by the cytochrome P450 system, such as warfarin, antipyrine, indomethacin, ibuprofen, phenytoin, propranolol, prednisone, diazepam, or clarithromycin in healthy subjects.

## ADVERSE REACTIONS

- Abdominal Pain, diarrhoea, nausea, headache may rarely occur

## DOSAGE AND ADMINISTRATION

- Short-Term Treatment of Duodenal Ulcers: one capsule daily for 4 weeks.

- H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence:

*Triple Therapy:* one capsule twice daily (q12h) for 10 or 14 days

*Dual Therapy:* one capsule three times daily (q8h) for 14 days

- Short-Term Treatment of Benign Gastric Ulcer: one capsule daily for up to 8 weeks.

- Healing of NSAID-associated Gastric Ulcer: one capsule daily for 8 weeks.

- Short -Term Treatment of Erosive Esophagitis: one capsule daily for up to 8 weeks.

- Pathological Hypersecretory Conditions Including Zollinger-Ellision Syndrome: two capsules once daily.

## HOW SUPPLIED

A box of 2 strips each of capsules.

## Produced by

Unipharma, El-Obour City, Egypt.