

Zoton

Lansoprazole Capsule

Presentation :

Zoton 30 : Each capsule contains Lansoprazole USP 30 mg (as enteric coated pellets).

Zoton 15 : Each capsule contains Lansoprazole USP 15 mg (as enteric coated pellets).

Description :

Lansoprazole is classified as a proton pump inhibitor. It belongs to a new class of antiseecretory agents, substituted benzimidazole group. It suppresses gastric acid secretion by specific inhibition of the H^+-K^+ ATPase enzyme system responsible for exchanging H^+ with K^+ at the secondary surface of the gastric parietal cell. Lansoprazole exerts an inhibitory effect on gastric acid for at least 24 hours, which allows a once-daily dosing schedule.

Indications :

Gastric ulcer, duodenal ulcer, peptic ulcer associated with *Helicobacter pylori*, NSAID associated peptic ulcer, gastro-oesophageal reflux disease, acid-related dyspepsia and Zollinger-Ellison syndrome.

Dosage and Administration :

Benign gastric ulcer : 30 mg daily in the morning for 8 weeks.

Duodenal ulcer : 30 mg daily in the morning for 4 weeks; maintenance 15 mg daily.

NSAID associated duodenal or gastric ulcer : 15-30 mg once daily for 4 weeks, followed by a further 4 weeks if not fully healed.

Zollinger-Ellison syndrome (and other hypersecretory conditions) : Initially 60 mg once daily adjusted according to response; daily doses of 120 mg or more given in two divided doses.

Gastro-oesophageal reflux disease : 30mg daily in the morning for 4 weeks, followed by a further 4 weeks if not fully healed; maintenance 15-30 mg daily.

Acid-related dyspepsia : 15-30 mg daily in the morning for 2-4 weeks.

TRIPLE THERAPY : In peptic ulcer associated with *H. pylori*.

Drug	Dose	Frequency	Duration
Lansoprazole	30 mg	BID	7-14 days
Clarithromycin	500 mg	BID	
Amoxicillin	1 gm	BID	

Average dose and doses range for adults and children

Adult : 30-60mg daily

Children : Children not recommended.

Dosing interval : Usually 30mg once daily (in 24 hours, specially in the morning), but in necessity 30mg Lansoprazole can be used twice daily (twelve hourly).

Average duration of time : The FDA has now approved it for a year.

Contraindications :

The use of Lansoprazole is contra-indicated in patients with a history of hypersensitivity to any of the ingredients of Lansoprazole capsules.

Precautions :

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 diseases 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.

Warnings

Lansoprazole capsule should be administered with care in the following patients--

- Patients with a history of drug hypersensitivity
- Patients with hepatic dysfunction
- Lansoprazole should only be used in pregnancy if the potential benefit justifies the possible risk to the fetus.
- It is advisable to avoid the administration of Lansoprazole capsule to nursing mothers.
- The safety of Lansoprazole capsule in children has not been established.

Adverse effects

Lansoprazole is well tolerated with adverse events generally being mild and transient. The most commonly reported adverse events are headache, dizziness, fatigue, and malaise. Gastrointestinal effects include diarrhea, constipation, abdominal pain, vomiting, flatulence, and dry or sore mouth or throat. Other reactions include arthralgia, myalgia, depression, peripheral oedema and rarely paraesthesia, blurred vision, test disturbances reported.

Overdose

There is no information on the effect of overdosage. However, Lansoprazole has been given at doses up to 120mg/day without significant adverse effects. Symptomatic and supportive therapy should be given as appropriate.

Use in pregnancy and lactation :

There are, no adequate or well-controlled studies in pregnant & lactating women. It should be used during pregnancy only if clearly needed.

Special conditions :

Paediatrics : Safety and effectiveness in children have not been established.

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

Renal Impairment : No dosage modification of Lansoprazole is required in patients with renal failure.

Hepatic Impairment : The daily dose should not exceed 30 mg.

Drug interactions :

Lansoprazole is metabolized through the cytochrome P450 system. Studies have shown that Lansoprazole does not have clinically significant interactions with Warfarin, Indomethacin, aspirin, ibuprofen, Prednisolone, antacids, or diazepam in healthy subjects. When Lansoprazole was administered concomitantly with theophylline, a minor increase (10%) in the clearance of theophylline was seen, which is unlikely to be of clinical concern. Nonetheless, individual patients may require adjustment of their theophylline dosage when Lansoprazole is started or stopped to ensure clinically effective blood levels.

Storage conditions :

Store below 25°C, protect from direct sunlight & heat.

Shelf-life :

2 years from the date of manufacturing.

Commercial pack :

Zoton 30 : Each box contains 5 Alu-Alu blister packs of 4 capsules.

Zoton 15 : Each box contains 3 blister packs of 10 capsules.



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The information given here is limited. For further information consult your doctor or pharmacist.