Indpro 30mg Capsules

(Lansoprazole) Capsules USP

Composition:
Each capsule contains:
Lansoprazole USP 30mg
(as enteric coated pellets)
Finished Product Specs.: USP

Description:
Lansoprazole is an antiulcer drug used for the short-term treatment of gastric ulcers or esophagitis, and for the long-term treatment of a pathological hyper-secretory condition known as Zollinger-Elllison Syndrome. Lansoprazole is a substituted benzimidazole, which contains a novel trimethoxy group that contributes to the increased lipid solubility and bioavailability of the molecule.

Pharmacology:
Mechanism of Action:
After oral administration Lansoprazole is converted into an active sulphonamide metabolite, which suppresses gastric acid secretion by inhibiting H^+/K^+ ATPase enzyme system of gastric parietal cells.

Pharmacodynamics:
Anti-secretory Activity:
After oral administration Lansoprazole significantly decreases:
1. The basal acid output
2. Meal stimulated gastric acid output
3. Gastrin stimulated acid output

Lansoprazole also significantly increases the mean gastric pH (towards alkaline side). Lansoprazole, exerts an inhibitory effect on gastric acid for at least 24 hours which allows a once daily dosing schedule. Lansoprazole does not antagonize H_2 or cholinergic receptors.

Other Gastric Effects in Humans:
Lansoprazole did not significantly affect mucosal blood flow in the fundus of the stomach. Lansoprazole increased serum pepsinogen levels and decreased pepsin activity under basal conditions and in response to meal stimulation or insulin injection.

Serum Gastrin Effects:
Suppression of gastric acid secretion stimulates the release of gastrin, the polypeptide. Gastrin stimulates the proliferation of cells in the acid secreting gastric mucosa. Therefore any drug that has effect on gastric acid secretion can have a secondary effect on rise in gastrin level. However Lansoprazole on long-term administration has shown to cause a non-significant increase in serum gastrin levels.

Prevention at Experimental Gastric Mucosal Damage:
Has shown to prevent aspirin (NSAID) induced gastric damage in rats.

Microbiology: Lansoprazole has been shown to be active against most strains of Helicobacter pylori in vitro. In vitro studies have shown that Lansoprazole is four times more potent than omeprazole in eradication of H. pylori.

Other Effects: No systemic effects of Lansoprazole have been found in humans.

Pharmacokinetic Properties:
Absorption: The absorption of Lansoprazole is rapid with mean Cmax occurring approximately 1.7 hours after oral dosing. The absolute bioavailability is over 80%. The mean plasma half-life was 1.5 (+1.0) hour.
Distribution: Lansoprazole is 97% bound to plasma proteins.
Metabolism: Lansoprazole is extensively metabolized in liver.
Elimination: Elimination occurs via biliary excretion.

Pharmacokinetics in Patients with Renal Impairment:
Patients with impaired renal function showed no references from healthy subjects. There is no alteration in the pharmacokinetics of Lansoprazole hence no dosage adjustment is required.

Pharmacokinetics in Patients with Hepatic impairment:
Patients with impaired hepatic function however had increases in mean AUC of up to 500 because of decreased metabolism and would therefore require reduced doses.

Pharmacokinetics in Elderly Patients: In elderly Patients there is no change in the pharmacokinetics of Lansoprazole hence no dosage adjustment is required.

Indications:
1. Short term treatment of Active duodenal ulcer
2. H.Pylori eradication to reduce the risk of duodenal ulcer recurrence
3. Maintenance of healed duodenal ulcers
4. Short-term treatment of active, benign gastric ulcer
5. Healing of NSAID - associated gastric ulcer
6. Risk reduction of NSAID-associated gastric ulcer
7. Gastro Esophageal Reflux disease (GERD)
8. Maintenance of Healing Erosive Esophagitis.
9. Pathological Hyper-secretory conditions, including Zollinger-Ellison Syndrome

Contra-indications:
1. Hypersensitive to Lansoprazole or any other component of the formulation.
2. Pregnancy and Lactation.
3. Severe Hepatic Disease.
4. Infants.

Special warnings and 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 is 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 now 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 30mg should not be exceeded. Treatment with acid-reducing drugs may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

Drug interaction:
Lansoprazole is shown to have no clinically significant drug interactions with other drugs. Sucralfate has been shown to delay absorption and reduce the bioavailability of Lansoprazole by about 17%. Lansoprazole should therefore be taken no less than 30 minutes before Sucralfate, and these drugs are to be used concomitantly.

Dosage and Directions for Use:

Gastric Ulcers	30mg once daily for 4-8 weeks
Reflux Esophagitis	30-60mg once daily for 4-8 weeks
Gastroesophageal reflux disease	30mg once daily for 8 weeks
Acid peptic disorder refractory to H_2 antagonist	30-60mg once daily for 8-12 weeks
Zollinger- Ellison Syndrome	Dose varies according to the severity of disorder
H. Pylori Eradication	30mg -Twice daily for 10-14 days
NSAID associated gastric ulcers	30mg - once daily for 8 weeks

Adverse Reactions:
Abdominal pain, diarrhoea and nausea/vomiting, headache, dermatological reactions are the most commonly observed side effects in less than 2% of patients using Lansoprazole. Most of the adverse effects are mild and do not necessitate withdrawal of treatment.

Effects on ability to drive and use machines:
Lansoprazole is not known to affect on ability to drive or operate machines.

Overdosage:
There is no information on the effect of overdosage. However, Lansoprazole has been given at doses up to 180mg/day without significant adverse effects. Symptomatic and supportive therapy should be given as appropriate.

Presentation:
Indpro 30mg capsules: Alu-Alu blister pack of 14 capsules.

Instructions:
- Store below 30°C.
- Protect from heat, light and moisture.
- To be sold on the prescription of a registered medical practitioner only.

Keep all medicines out of the reach of children.

Manufactured by :
Indus Pharma (Pvt.) Ltd.
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