TAKEPRON®

(Lansoprazole)

ACTION

Takepron (Lansoprazole) is an effective inhibitor of gastric acid secretion. Takepron specifically inhibits the H+/K+ATPase (proton pump) of the parietal cells in the gastric mucosa. Takepron is rapidly absorbed after oral administration with peak plasma concentrations achieved within approximately 1.5 hours; Lansoprazole is substantially metabolized by the liver.

INDICATIONS

Takepron is effective in the treatment of acid-related disorders of the upper gastrointestinal tract, with the benefit of rapid symptom relief:

- Short –Term Treatment of Active Duodenal Ulcer: Lansoprazole is indicated for short term treatment (for 4 weeks) for healing and symptoms relief of active duodenal ulcer.
- H.pylori Eradication: to reduce the risk of duodenal ulcer recurrence using either of:
  - Triple Therapy: combination of Lansoprazole, amoxicillin, and clarithromycin.
  - Dual Therapy: combination of Lansoprazole and amoxicillin.
- Maintenance of Healed Duodenal Ulcers: Lansoprazole is indicated in healing of Duodenal Ulcer. Controlled studies do not extend beyond 12 months
- Short –Term Treatment of Active Benign Gastric Ulcer Lansoprazole is indicated for short term treatment (up to 8 weeks) for healing and symptoms relief of active benign gastric ulcer.
- Healing of NSAID-Associated Gastric Ulcer Lansoprazole is indicated for treatment of NSAID-associated gastric ulcer in patients who continue NSAID use.
- Risk Reduction of NSAID-Associated Gastric Ulcer
- Gastroesophageal Reflux Disease (GERD)
  - Short Term Treatment of Symptomatic (GERD) Lansoprazole is indicated for the treatment of heartburn and other symptoms associated with GERD
  - Short Term Treatment of Erosive Esophagitis
- Maintenance of Healing of Erosive Esophagitis
- Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome

DOSAGE AND ADMINISTRATION

To achieve the optimal effect, Takepron should be administered before meals.

Adults:

Duodenal ulcer:
15-30 mg once daily for 4 weeks.

Benign gastric ulcer:
30 mg once daily for up to 8 weeks.

Gastroesophageal Reflux Disease (GERD):
30 mg once daily for up to 8 weeks. The majority of patients will be healed after the first course. For those patients not fully healed at this time, a further 8 weeks treatment at the same dosage should be given.

Zollinger-Ellison Syndrome:
60 mg once daily initially, dose may then be adjusted according to individual needs.

Elderly: dose adjustment is not required in the elderly.

Maintenance therapy:
Takepron 15 mg is given once daily to prevent relapse.

H. pylori eradication:
Takepron 30 mg is given twice daily for 7-10 days with antibiotics.

CONTRAINDICATIONS

Hypersensitivity to Lansoprazole.

WARNINGS

Takepron should be administrated with caution to patients with severe hepatic disorder.

PRECAUTIONS:

Pregnancy:
Category B.However there is no adequate or well controlled studies in pregnant woman. Because animal reproduction studies are not always predictive of human response, this drug could be used during pregnancy only if clearly needed.

Nursing Mothers:
Lansoprazole or its metabolites are excreted in the milk of rats,it is not known whether Lansoprazole is excreted in human milk. The decision should be made whether to discontinue nursing or to discontinue Lansoprazole,taking into account the importance of Lansoprazole to the mother.

Pediatric Use:
The safety and effectiveness of Lansoprazole have been established in pediatric patients 1 to 17 years of age for short term treatment of symptomatic GERD and erosive esophagitis. The adverse events profile in pediatric patients is similar to that of adults. There were no adverse events reported in U.S clinical studies that were not previously observed in adults. The safety and effectiveness of Lansoprazole in patients less than 1 year of age hasn't been established.

- 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.
- Regular medical follow up should be performed including examinations of the stomach and/or esophagus (Endoscopy, Radiography).

Drug Interactions:

- Lansoprazole is metabolized through the cytochrome P450 system, specifically through the CYP3A and CYP2C19 isoenzymes.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. A minor increase (10%) in the clearance of theophlline was seen.
- Antacids may reduce the bioavailability of Lansoprazole and should therefore be given one hour apart.
- Interaction with Atazanavir has been reported, by decreasing Atazanavir's systemic concentration. Therefore, Lansoprazole should not be coadministered with Atazanavir.

SIDE EFFECTS

Adverse events are generally transient and include diarrhea, abdominal pain, dyspepsia, nausea, vomiting, dry mouth, flatulence, constipation, headache, dizziness, fatigue, rash, urticaria and pruritus. Increases in liver function test values have been observed. Leukopenia and thrombocytopenia may occur. Microscopic colitis and interstitial nephritis.

OVERDOSAGE

Treatment is supportive and symptomatic.

STORAGE

Store below 30°C, away from light and humidity.
Close the bottle carefully after each use.

PRESENTATIONS

Capsules:

TAKEPRON 15:	Lansoprazole 15 mg/capsule
TAKEPRON 30:	Lansoprazole 30 mg/capsule

Excipients: magnesium carbonate, nonpareil, sucrose, corn starch, hydroxypropyl cellulose, methacrylic acid & ethyl acetate copolymer, talc, macrogol 6000, titanium dioxide, polysorbate 80, anhydrous colloidal silica

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold 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.

Takeda

Manufactured by:
The Arab Pharmaceutical Manufacturing Co. Ltd., Sult - Jordan
in technical cooperation with:
Takeda Pharmaceutical Co. Ltd., Osaka - Japan

العربية APM

Keep medicament out of the reach of children

2INTKP-AE-06/2007