

# Helicon Kit

H. pylori Kit

## PRESENTATION



Each HELICON KIT contains

One Lansoprazole USP 30 mg capsule  
(as enteric coated pellets)

One Clarithromycin USP 500 mg tablet

Two Amoxicillin BP 500 mg capsules

### DESCRIPTION

The role of *H. pylori* in the pathogenesis of peptic ulcer is no longer disputed and eradication of this infection is now regarded as the first line treatment of this common disorder because *H. pylori* is responsible for duodenal ulcer in more than 95 % and over 85 % of gastric ulcer diseases. Complete healing without *H. pylori* eradication causes relapse rate over 95% in one year but with eradication of *H. pylori*, the relapse rate is less than 5%. A clinical trial with triple therapy consisting lansoprazole (30 mg bid), Amoxicillin (1 gm bid) and clarithromycin (500 mg bid) for 7-14 days showed *H. pylori* eradication in 95.2% of patients, after 7 days treatment, healing of ulcers was obtained in 98% cases.

### INDICATIONS AND USAGE

Helicon Kit is indicated in the eradication of *H. pylori* in active chronic gastritis, duodenal and gastric ulcers.

### DOSAGE

Each Helicon kit twice daily for 7-14 days or as per the physician's advice.

### CONTRAINDICATIONS

The Helicon kit is contraindicated in patients with known hypersensitivity to any of its component.

### PRECAUTIONS

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on Amoxicillin therapy. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity. Clarithromycin should not be used in pregnant women except in clinical circumstances where no alternative therapy is appropriate.

### DRUG INTERACTION

Lansoprazole is metabolized through the cytochrome p-450 system, specifically through the CYP3A and CYP2C19 isozymes. Studies have shown that lansoprazole does not have clinically significant interactions with other drugs metabolized by the cytochrome p-450 system, such as warfarin, antipyrine, indomethacin, ibuprofen, phenytoin,

propranolol, prednisolone, diazepam, clarithromycin, or terfenadine in healthy subjects. Clarithromycin use in patients who are receiving theophylline may be associated with an increase of serum theophylline concentrations.

### PREGNANCY & NURSING MOTHERS

There were no adequate and well controlled studies of Helicon kit in pregnant women. Helicon kit should be used during pregnancy only if the potential benefit justifies the potential risk to the mother.

Amoxicillin is excreted in human milk in very small amounts. Because of the potential for serious adverse reactions in nursing infants from Helicon kit, a decision should be made whether to discontinue nursing or to discontinue the drug therapy, taking into account the importance of the therapy to the mother.

### GERIATRIC USE

Elderly patients may suffer from asymptomatic renal and hepatic dysfunction. Care should be taken when administering Helicon kit to this patient population.

### ADVERSE REACTIONS

Adverse reactions which were reported as possibly or probably related to treatment (<3%) in clinical trials when all three components of this therapy were given concomitantly are listed below and divided by body systems. Digestive system : nausea, vomiting, diarrhoea, dark stool, glossitis, oral moniliasis, stomatitis, tongue discoloration, Musculoskeletal System : myalgia, Nervous System : confusion, headache, dizziness, Skin : skin reactions, Urological System : vaginitis, vaginal moniliasis.

### STORAGE

Store in a cool and dry place.

### COMMERCIAL PACK

Please refer to outer carton.

Manufactured by:

