

HELI-KIT®

EACH HELI-KIT CONTAINS:

2. Lansoprazole Capsule BP
2. Clarithromycin Table
2. Tinidazole Tablets

HELI-KIT

Composition

Each kit contains two capsules of Lansoprazole, two tablets of Clarithromycin and Two tables of Tinidazole

(A) 2 LANSOPRAZOLE CAPSULE BP

Each Capsule contains:

Lansoprazole BP 30mg
(enteric coated granules)

(B) 2CLARITHROMYCIN TABLETS USP

Each film coated Tablet Contains:

Clarithromycin USP 250mg
Colour: Titanium Dioxide BP

(C) 2TINIDAZOLE TABLETS

Each Film Coated Tablets Contains:

Tinidazole USP 500mg
Colour: Lake Quinoline Yellow &
Titanium Dioxide BP

THE PROBLEM: H. PYLORI

- ▶ Responsible for 80% gastric ulcer and 90% of duodental ulcers.
- ▶ Most vital aetiological factor in Peptic ulcer disease.
- ▶ Eradication of H. pylori will cure peptic ulcer and decrease relapse
- ▶ Eradication of H.pylori reduces length of therapy and total cost of treatment
- ▶ Eradication of H. pylori reduces the need for acid suppression

The Solution

HELI-KIT®

Will eradicate H.Pylori

Tinidazole (500mg)
Lansoprazole(30mg)

Clarithromycin (250mg)

DESCRIPTION

Helicobacter pylori is a gram-negative, spiral-shaped bacterium with a worldwide prevalence. Helicobacter pylori is implicated in the etiology of gastritis. Conventional histamine-2 receptor antagonists do not suppress or eradicate Helicobacter pylori and have a high rate of ulcer recurrence. Monotherapy using bismuth compounds or antimicrobials is not very effective with an eradication rate not more than 15-20%. Dual therapy with bismuth salt plus antimicrobials agent eradicate Helicobacter pylori in only 50% of cases. The standard triple therapy regimens comprising a bismuth salt, metronidazole or tinidazole and tetracycline or amoxicillin has proved to be effective for eradicating Helicobacter pylori. But the major disadvantage of bismuth triple therapy is compliance, which may be compromised by a patient having to take 15 tablets a day. There are significant side effects including malaise, sour mouth, diarrhea, nausea and potential for a disulfiram-like reaction when metronidazole and alcohol are taken concurrently which may be severe enough again to affect compliance.

Newer triple therapies including proton pump inhibitor such as lansoprazole plus Clarithromycin and Tinidazole may serve as shorter, simple and effective drug regimen for the eradication of Helicobacter pylori.

Lansoprazole is a substituted benzimidazole gastric ant secretory agent. Lansoprazole binds to H⁺K⁺ ATP as in gastric parietal cells, inactivation of this enzyme system blocks the final step in the secretion of hydrochloric acid by these cells. Lansoprazole also inhibits basal and stimulated gastric acid secretion. The MIC of Lansoprazole and sulfonamide metabolites ranges from 0.6mg/L to 2.5mg/l. It is four times more potent than Omeprazole. The selective activity of lansoprazole against H. pylori, its anti-urease effects, and its stability in acidic and neutral environment are likely to be important factors in the treatment of H. pylori infection.

Clarithromycin a potent macrolide, exerts its anti-bacterial action by binding to the 50 S Ribosomal unit of susceptible bacteria and suppresses protein synthesis.

Clarithromycin has good in vitro activity (MIC90 Value 0.03mg/l against H. pylori, which makes it suitable for incorporation into regimen for the eradication of H. pylori infection.

Tinidazole 5-nitromidazole is more potent and long acting compared to metronidazole. It is active against protozoal and anaerobic bacterial infection. Tinidazole is considered to be an active anti-microbial agent against H.pylor and exerts rapid bactericidal actions. Tinidazole acts by damage of DNA strands or inhibition of their synthesis.

INDICATION

HELI-KIT in the indication in the eradication of H.pylori in active chronic gastritis, duodenal and gastric ulcers.

DOSAGE AND ADMINISTRATION

One HELI-KIT pack contains 2 capsules of lansoprazole (30mg), 2 tablets of clarithromycin (250mg) and 2 tablets of Tinidazole (500mg). One pack is one-day treatment. From this specially designed pack, one capsule of Lansoprazole, one tablet of Tinidazole and one tablet of Clarithromycin is to be taken in the morning and similarly one each in the evening. The treatment should be continued for minimum of 7days.

CONTRAINDICATIONS

Hypersensitivity to Lansoprazole or Clarithmycin or Tinidazole.

SIDE EFFECT

The drugs of the comb kit are well tolerated. Side effects include nausea, vomiting, diarrhea and abdominal pain. Other rare side effects include headache, skin rash, metallic taste, rarely glossitis, urticarial, eruptions, moderate leucopenia.

OVERDOSAGE

There are no studies on over dosage. In case of over dosage management should be with symptomatic and supportive therapy.

STORAGE

Store in a cool dry place

PRESENTATION

Lansoprazole, Clarithromycin and Tinidazole are offered in a special comb kit. Each kit pack of HELI-KIT contains 2 capsules of Lansoprazole (30mg), 2 tablets of Clarithromycin (250mg) and 2 tablets of Tinidazole (500mg).

Each box contains 10 kits.

RECOMMENDATION

Read leaflet carefully before use. For further information, please ask your doctor's advice.

HELI-KIT is to be only used on doctor's prescription.

Marketed by:

Reals

Reals Pharmaceuticals Ltd.
1, Alh. Junaid Dosunmu Str,
CBD, Alausa, Ikeja, Lagos.