Lansoprazole Delayed Release Capsules USP, Clarithromycin Tablets USP & Tinidazole Tablets (Kit Pack)

LCT Kit

IDENTIFICATION:

(A) Lansoprazole Delayed-Release Capsules USP 30 mg : Black/Orange size "2" capsule containing white colour enteric coated tablets.

(B) Clarithromycin Tablets USP 250 mg : Yellow colour, capsule shape, plain on both side of film coated tablet.

(C) Tinidazole Tablets 500 mg: White colour, capsule shape, plain on both side of film coated tablet.

COMPOSITION :

Each combipack contains :

A) 2 Nos. Lansoprazole Delayed Release Capsules USP 30 mg
Each hard gelatin capsule contains:
Lansoprazole USP 30 mg
(As Enteric coated granules)
Excipients Q.S.
Approved colours used in empty capsule shell.

B) 2 Nos. Clarithromycin Tablets USP 250 mg
Each film coated tablet contains:
Clarithromycin USP 250 mg
Excipients Q.S.
Colour: Lake of Quinoline Yellow & Titanium Dioxide BP

C) 2 Nos. Tinidazole Tablets 500 mg
Each film coated tablet contains:
Tinidazole BP 500 mg
Excipients Q.S.
Colour: Titanium Dioxide BP

THERAPEUTIC CLASS :

Proton Pump Inhibitor, Anti-bacterial, Antiprotozoal.

PHARMACOLOGICAL ACTION :

Lansoprazole: Lansoprazole is an inhibitor of the gastric H^+,K^+-ATPase (proton pump). Lansoprazole inhibits gastric acid secretion in a dose related manner irrespective of the source of stimulation. Gastric secretory functions recover gradually following discontinuation of the medicine. Lansoprazole has no effect on histamine, gastrin or cholinergic receptors.

Clarithromycin: Clarithromycin is a semi-synthetic derivative of erythromycin A. It exerts its antibacterial action by binding to the 50s ribosomal sub-unit of susceptible bacteria and suppresses protein synthesis. It is highly potent against a wide variety of aerobic and anaerobic gram-positive and gram-negative organisms. The minimum inhibitory concentrations (MICs) of clarithromycin are generally two-fold lower than the MICs of erythromycin.

Tinidazole: Tinidazole is a nitroimidazole drug. Tinidazole is bactericidal, amoebicidal and trichomonicidal in action. Tinidazole interferes in nucleic acid synthesis DNA of cells and causes cellular death.

Pharmacokinetics :

Lansoprazole : It exhibits high (80-90%) bioavailability with a single dose. As a result, effective acid inhibition is achieved rapidly. Peak plasma levels occurred within 1.5 to 2.0 hours. The plasma elimination half-life ranges from 1 to 2 hours following single or multiple doses in healthy subjects. There is no evidence of accumulation following multiple doses in healthy subjects. The plasma protein binding is 97%. Following absorption, lansoprazole is extensively metabolized and is excreted by both the renal and biliary route. A study with ^{14}C-labelled lansoprazole indicated that up to 50% of the dose was excreted in the urine. Lansoprazole is metabolized substantially by the liver.

Clarithromycin : Clarithromycin is rapidly and well absorbed from the gastro-intestinal tract after oral administration of Clarithromycin tablets. The microbiologically active metabolite 14-hydroxyclarithromycin is formed by first pass metabolism. Clarithromycin may be given without regard to meals as food does not affect the extent of bioavailability of Clarithromycin tablets. Food does slightly delay the onset of absorption of clarithromycin and formation of the 14-hydroxymetabolite. The pharmacokinetics of clarithromycin are non linear; however, steady-state is attained within 2 days of dosing. At 250 mg b.i.d. 15-20% of unchanged drug is excreted in the urine. With 500 mg b.i.d. daily dosing urinary excretion is greater (approximately 36%). The 14-hydroxyclarithromycin is the major urinary metabolite and accounts for 10-15% of the dose. Most of the remainder of the dose is eliminated in the faeces, primarily via the bile. 5-10% of the parent drug is recovered from the feces.

Clarithromycin is 80% bound to plasma proteins at therapeutic levels.

Tinidazole : It Rapidly and completely absorbed under fasting conditions. Administration with food results in a delay in T_{max} and a decline in $C_{max.}$ Plasma protein binding is 12%. It is significantly metabolized in humans prior to excretion. Elimination half-life is 13.2 ± 1.4 hours. Plasma half-life is 12 to 14 hours.

INDICATIONS :

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

CONTRAINDICATIONS :

Hypersensitivity to lansoprazole or tinidazole or clarithromycin.

ADVERSE EFFECTS :

The drugs of the LCT Kit are well tolerated. Side effects include nausea, vomiting, diarrhoea and abdominal pain. Other rare side effects include headache, skin rash, metallic taste (change in taste), rarely glossitis, stomatitis, urticaria, eruptions and moderate leucopenia.

PRECAUTIONS & WARNINGS :

Lansoprazole: 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.

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.

Decreased gastric acidity due to any means, including proton pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid-reducing drugs may lead to a slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

Tinidazole: Alcoholic beverages should be avoided during tinidazole therapy because of the

possibility of a disulfiram-like reaction (flushing, abdominal cramps, vomiting, tachycardia). Alcohol should be avoided until 72 hours after discontinuing tinidazole.
Drugs of similar chemical structure have also produced various neurological disturbances such as dizziness, vertigo, in-coordination and ataxia. If during therapy with tinidazole abnormal neurological signs develop, therapy should be discontinued.
Clarithromycin: Pseudomembranous colitis has occurred with nearly all antibacterial agents including clarithromycin and may range in severity from mild to life-threatening. Therefore it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of LCT Kit.
Pregnancy: Lansoprazole, Tinidazole, Clarithromycin : There are no well controlled studies of lansoprazole or tinidazole or clarithromycin in pregnant women. Clarithromycin is not indicated during pregnancy, Hence this combination is not indicated in pregnancy.
Lactation: It is not known whether lansoprazole or tinidazole or clarithromycin is excreted in breast
milk. Caution should be exercised when administering to a nursing woman.
Paediatric Use: Safety and effectiveness of LCT Kit in paediatric population has not been established.
Renal And Hepatic impairment: Caution should be exercised while administering LCT Kit with renal impairment and hepatic disease.

DOSAGE & ADMINISTRATION :
One LCT Kit pack contains two capsules of lansoprazole (30 mg), two tablets of tinidazole (500 mg) and two tablets of clarithromycin (250 mg). One pack is for 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 duration of therapy recommended is for seven days.

DRUG INTERACTIONS :
Lansoprazole: Lansoprazole is hepatically metabolized and studies indicate that it is a weak inducer of Cytochrome P450. There is the possibility of interaction with drugs which are metabolized by the liver. Caution should be exercised when oral contraceptives and preparations such as phenytoin, carbamazepine, theophylline, or warfarin are taken concomitantly with the administration of lansoprazole. No clinically significant effects on NSAIDs or diazepam have been found.
Antacids and sucralfate may reduce the bioavailability of lansoprazole and should, therefore, not be taken within an hour of lansoprazole.
Tinidazole: Drugs of similar chemical structure have been shown to potentiate the effects of oral anticoagulants. Prothrombin times should be closely monitored and adjustments to the dose of the anticoagulant should be made as necessary.
Clarithromycin: Clarithromycin use in patients who are receiving theophylline may be associated with an increase in serum theophylline concentrations.
Concomitant administration of single doses of clarithromycin and carbamazepine has been shown to result in increased plasma concentrations of carbamazepine.
The use of clarithromycin in patients receiving warfarin may result in potentiation of the effects of warfarin. Prothrombin time should be frequently monitored in these patients.
The effects of digoxin may be potentiated with concomitant administration of clarithromycin.
Concomitant administration of single dose of clarithromycin and terfenadine have been shown to result in increased plasma concentrations of terfenadine.
Clarithromycin should not be given to patients receiving terfenadine therapy who have pre-existing cardiac abnormalities (arrhythmia, bradycardia, QT interval prolongation, ischemic

heart disease, congestive heart failure) or electrolyte disturbances.
The theoretical possibility of ergotism contraindicates the concurrent use of clarithromycin with ergot derivatives.
Clarithromycin increases the serum concentration of cyclosporin hence the dosage of latter may be reduced to avoid renal toxicity.
The use of clarithromycin in patients concurrently taking drugs metabolized by the cytochrome P450 system may be associated with elevations in serum levels of these drugs.

OVERDOSAGE :
In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required.

EXCIPIENTS:
Clarithromycin Tablets USP 250 mg
Microcrystalline Cellulose, Maize Starch, Povidone, Isopropyl Alcohol, Sodium Starch Glycolate, Croscarmellose Sodium, Purified Talc, Magnesium Stearate, Isopropyl Alcohol, Ethylcellulose, Titanium Dioxide
Colour Quinoline Yellow Lake, Hypromellose, Propylene Glycol, Dichloromethane
Tinidazole Tablets 500 mg
Maize Starch, Hypromellose, Liquid Sorbitol, Sodium Starch Glycolate, Calcium Hydrogen Phosphate, Microcrystalline Cellulose, Magnesium Stearate, Ethylcellulose, Isopropyl Alcohol, Titanium Dioxide, Macrogols, Purified Talc, Dichloromethane

PRESENTATION :
2 Nos. Lansoprazole Capsules + 2 Nos. Clarithromycin Tablets + 2 Nos. Tinidazole Tablets in one Blister pack.

STORAGE CONDITION :
Store under normal storage conditions (15°C-30°C). Protect from moisture.

SHELF LIFE :
24 Months

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