

Trio-Clar[®]

Composition:

Green capsules: each green capsule contains
Yellow capsules: each yellow capsule contains
White tablets: each White tablet contains

Omeprazole	20 mg
Tinidazole	500 mg
Clarithromycin	500 mg

Properties:

Trio-Clar represents carefully selected and balanced therapeutic regimen for the management of both gastric and duodenal ulcers.

It achieves powerful eradication of the common micro-organism which is proved to be associated with the following gastrointestinal diseases:

Duodenal ulcer, gastric ulcer, antral gastritis and gastric carcinoma.

In addition, *H. pylori* infection is implicated in other conditions such as gastric lymphoma and non-ulcer dyspepsia.

Trio-Clar offers such proper management of *H. pylori* by combining: a long-acting antibiotic (clarithromycin), an efficient proton pump inhibitor (omeprazole) and a powerful agent against anaerobes (tinidazole).

Clarithromycin: is a semi-synthetic macrolide. It is active against a variety of aerobic and anaerobic gm + ve, gm-ve organisms. It exerts its action by binding to the 50 S ribosomal sub-unit of susceptible organisms; thus inhibiting microbial protein synthesis.

Omeprazole: this is one of a new class of anti-secretory compounds which suppresses gastric acid secretion by specific inhibition of the H^+/K^+ ATPase enzymes (the so called proton pump).

Proton pump inhibitors are much more effective in healing of peptic ulcers than traditional H_2 -histamine receptor antagonists.

Tinidazole: this is the most potent member of the nitroimidazoles possessing a wide spectrum against anaerobic bacteria as well as protozoa. The MIC against *H. pylori* is 4 mg/L. Because of its high serum and tissue levels, it is highly efficient in the eradication of *H. pylori*.

Indications & usage:

Trio-Clar as a triple therapy is indicated for the treatment of :-

- Patients presented with clinical symptoms of peptic ulcer
- Prevent recurrence of peptic ulcer
- Ulcer resistant for healing with anti-secretory treatment

Drug Interactions:

1- Theophylline: Use of clarithromycin with theophylline may be associated with an increase of serum theophylline.

2- Carbamazepine: Concomitant administration of single doses of clarithromycin & carbamazepine has been shown to result in increased plasma concentration of carbamazepine.

3- Terfenadine: Concomitant administration of clarithromycin with terfenadine causes high concentration of the active metabolite of terfenadine.

4- Ranitidine: Causes increased plasma ranitidine concentrations.

5- Ergotamine or dihydroergotamine: Concurrent use has been associated in some patients with acute ergot toxicity.

6- Interaction of omeprazole with other drugs:-

Anticoagulants (blood thinners), Diazepam and Phenytoin [Use with omeprazole may cause high blood levels of these medicines, which may increase the chance of side effects].

Adverse reactions:

All ingredients of **Trio-Clar** are usually well tolerated. However, certain precautions must be considered regarding each ingredient as follows:

Omeprazole: This compound is generally well tolerated. Most frequently reported adverse effects (1%) are diarrhea, skin rash and headache. Bioavailability may also be increased in the elderly patients with renal impairment as there are some changes observed in pharmacokinetics.

Tinidazole: Reports of minor reactions including urticaria, metallic taste and mild nausea. These usually disappear after the initial treatment.

Clarithromycin: The majority of side effects observed in clinical trials were mild and transient in nature They include diarrhea . Some people get headach or rash However, these are rarely sever enough to justify discontinuation of treatment.

Contra-Indication:

During pregnancy & lactation: it is recommended to avoid using the drug as there is not enough data regarding its use during pregnancy & lactation.

The drug is contra-indicated in patients with known hypersensitivity to one of the product ingredients in addition to any macrolide antibiotic.

Administration of Trio-Clar with cisapride or terfenadine is contraindicated as this may result in cardiac arrhythmias.

Administration & Dosage:

The recommended adult dose is 500 mg Clarithromycin, 20 mg Omeprazole and 500 mg Tinidazole; all given twice daily for 1-2 weeks.

Package :

Box of 7 strips, each strip contains 2 capsules of Tinidazole, 2 capsules of Omeprazole and 2 tablets of Clarithromycin.

Storage:

Keep in the room temperature (25°) or below.
Keep out of reach of children.

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