

**Composition:**  
Clarithromycin

**Excipients:** Tablets (250, 500): Sodium laurilsulphate, maize starch, crosscarmellose sodium, povidone, pregelatinised starch, microcrystalline cellulose, colloidal anhydrous silica, talc, magnesium stearate, opadry white and FD&C Yellow No.10. Suspension: Xanthan gum, ammonium glycyrrhizinate, hydroxypropyl methylcellulose, sodium laurilsulfate, methyl parahydroxy benzoate, saccharin sodium, strawberry powder flavour, citric acid monohydrate and sucrose fine powder.

**Properties:**

**Macromax<sup>®</sup>** is a semi-synthetic macrolide antibiotic. It is rapidly absorbed from the gastrointestinal tract after oral administration. Food slightly delays but does not affect the extent of absorption. In the liver, it is converted to the antimicrobially active metabolite, 14-hydroxy-clarithromycin, they distribute readily into body tissues and fluids, excluding CNS. Because of high intracellular concentrations, tissue concentrations are higher than serum concentrations.

**Mechanism of action:**

**Macromax<sup>®</sup>** exerts its antibacterial action by inhibition of protein synthesis, its metabolite is twice as active as the parent compound against certain organisms.

**Antimicrobial activity:**

**Macromax<sup>®</sup>** is highly potent against a wide variety of aerobic and anaerobic organisms, as well as most *Mycobacterium Avium Complex (MAC)*, including:

*Bacteroides fragilis, Bordetella pertussis, Campylobacter jejuni, Chlamydia pneumoniae, Chlamydia trachomatis, Clostridium parfringens, Haemophilus influenzae, Haemophilus parainfluenzae, Helicobacter pylori, Legionella pneumophila, Listeria monocytogenes, Moraxella catarrhalis, Mycobacterium avium, Mycobacterium chelonae, Mycobacterium fortuitum, Mycobacterium intracellulare, Mycobacterium kansasii, Mycobacterium leprae, Mycoplasma pneumoniae, Neisseria gonorrhoea, Peptococcus spp., Peptostreptococcus spp., Propionibacterium acnes, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans and Ureaplasma urealyticum.*

**Indications:**

Treatment of infections caused by pathogens sensitive to clarithromycin including:

**Upper respiratory tract infections:** Tonsillitis, pharyngitis, sinusitis and acute otitis media.

**Lower respiratory tract infections:** Acute and chronic bronchitis, bacterial pneumonia and atypical pneumonia.

**Skin infections:** Impetigo, erysipelas, folliculitis, furunculosis and septic wounds.

**Helicobacter pylori infections:** Peptic ulcer disease.

**Other:** Treatment and prevention of disseminated mycobacterial infections due to MAC disease.

**Dosage and administration:**  
- Adults: The usual dose of **Macromax<sup>®</sup>** is (250 – 500 mg) every 12 hours for 1-2 weeks.

**H. pylori eradication clarithromycin-included regimens**

	Macromax <sup>®</sup>	Lansoprazole	Amoxicillin	Omeprazole	RBC	Duration (days)
DUAL THERAPY	500 mg bid	-	-	40 mg qd	-	14
	500 mg bid or tid	-	-	-	400 mg bid	14
TRIPLE THERAPY	500 mg bid	30 mg bid	1 g bid	-	-	10 – 14
	500 mg bid	-	1 g bid	20 mg bid	-	10

RBC: Ranitidine Eternum Citrate  
Id: Three times daily, bid: Twice daily, qd: Once daily

- Children (6 months – 12 years): The recommended dose is 15 mg/kg/day in two divided doses for 10 days:

Child weight (kg)	Dose
5 – 10	2.5 ml q 12 h
11 – 20	5 ml q 12 h
21 – 30	7.5 ml q 12 h
>30	10 ml q 12 h

- Renal impairment (creatinine clearance <30 ml/min): The dosage should be halved or the dosing interval doubled.

- **Macromax<sup>®</sup>** may be administered without dosage adjustment in the presence of hepatic impairment.

- Dosage should not be continued beyond 14 days.

**Contraindications:**

- Hypersensitivity to macrolides (clarithromycin), or any component of this product.

**Drug interactions:**

- Carbamazepine: Carbamazepine plasma levels should be monitored.

- Warfarin: Prothrombin time should be frequently monitored.

- Zidovudine: Staggering the doses of clarithromycin and zidovudine by 1–2 hours.

- Clarithromycin increases the serum concentrations of the drugs metabolized by the cytochrome P450, theophylline, digoxin, terfenadine, cisapride, astemizole and pimozide upon concomitant use.

**Warnings:**

Safety and efficacy have not been established for up to 6 months of age.

**Precautions:**

- Caution should be considered in patients with impaired hepatic or renal function.

- Prolonged use of clarithromycin may result in overgrowth of non-susceptible bacteria or fungi.

- **Pregnancy:** There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

- **Lactation:** It is not known whether clarithromycin is excreted in human milk.

**Adverse reactions:**

- Incidence of GI disturbances and allergic reactions has been reported.

- Using macrolides, transient and reversible of SGOT & SGPT is possible. Like with other antibiotics, superinfection by resistant bacteria or fungi can rarely arise.

- There have been reports of transient CNS adverse reactions.

**Overdosage:**

The ingestion of large amounts of clarithromycin can be expected to produce gastrointestinal symptoms; treatment includes symptomatic and supportive care.

**Information for the patient:**

- **Macromax<sup>®</sup>** may be given without regard to meals.

- Do not refrigerate oral suspension.

- Finish the whole medication course.

**Presentations:**

- **Macromax<sup>®</sup>** 250 Tablet: Each film coated tablet contains 250 mg Clarithromycin in packs of 14 tablets.

- **Macromax<sup>®</sup>** 500 Tablet: Each film coated tablet contains 500 mg Clarithromycin in packs of 14 tablets and 20 tablets.

- **Macromax<sup>®</sup>** Suspension: Each 5 ml of reconstituted suspension contains 125 mg Clarithromycin in bottles of 60 ml.

\* Some presentations may not be available in certain countries.

(This is a medication - keep medications out of the reach of children)

• Medication is a product that affects your health, and its consumption contrary to instructions is dangerous for you.  
• Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medication.  
• 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.

Last update: 3/2007



Hayat Pharmaceutical Industries Co. PLC  
P.O.Box 1564  
Amman 11118 Jordan