

Claricin®

Tablet/Powder for Suspension

Clarithromycin USP

DESCRIPTION

Claricin® (Clarithromycin) is an antibiotic of the macrolide family and is a semisynthetic derivative of erythromycin. Claricin® (Clarithromycin) is rapidly absorbed from the gastrointestinal tract. It exerts its antibacterial action by binding to the 50S ribosomal subunit of susceptible bacteria and suppresses protein synthesis. It is highly effective against a wide variety of aerobic and anaerobic gram-positive and gram-negative organisms.

COMPOSITION

Tablet 250 : Each film-coated tablet contains Clarithromycin USP 250 mg.

Tablet 500 : Each film-coated tablet contains Clarithromycin USP 500 mg.

Powder for Suspension : After reconstitution each 5 ml suspension contains Clarithromycin USP 125 mg.

INDICATIONS

- **Lower respiratory tract infections:** Acute and chronic bronchitis, pneumonia.
- **Upper respiratory tract infections:** Sinusitis, pharyngitis, acute and chronic otitis media.
- Skin and soft tissue infections of mild to moderate severity and other infections caused by susceptible micro-organisms.
- Claricin® is also indicated as adjunct in the treatment of duodenal ulcers for the eradication of *H. pylori*.
- Disseminated or localized mycobacterial infections due to *Mycobacterium avium* or *Mycobacterium intracellulare*. Localized infections due to *Mycobacterium chelonae*, *Mycobacterium fortuitum*, or *Mycobacterium kansasii*.

DOSAGE AND ADMINISTRATION

Adults :

Recommended dosage in adults is 250 mg every 12 hours for 7 days. In severe cases, dosage may be increased up to 500 mg every 12 hours for up to 14 days. Eradication of *H. pylori* Claricin® 500 mg thrice daily with Omeprazole 40 mg once daily followed by Omeprazole 20 mg once daily (2 weeks regimen). Amoxycillin or Tetracycline to be added with the above regimen as per the suggestion of The American College of Gastroenterology. Or Omeprazole 20 mg twice daily, Claricin® 500 mg twice daily and Amoxycillin 1 g twice daily (1 week regimen).

Children :

The normal daily dose of children aged 6 months and above is 15 mg per kg of weight, taking half the daily dose in the morning and the other half in the evening. The dose for children weighing less than 8 kg must be calculated accurately according to the body weight.

Weight (kg)	Age (years)	Measuring spoon (per day) 125mg/5 ml
8-11	0.5-2	2×1/2
12-19	2-4	2×1
20-29	4-8	2×1 1/2
30-40	8-12	2 x 2

The suspension should be swallowed quickly, followed by a small amount of liquid.

Patients with renal failure and liver disease :

A dose reduction of Clarithromycin is recommended for patients with creatine clearance rates of <30ml per min. Dosage adjustment is not necessary for patients with impaired hepatic function. Food does not influence the absorption of it. Duration of treatment is 7-10 days.

OR AS DIRECTED BY THE PHYSICIAN.

SIDE EFFECTS

Clarithromycin is generally well tolerated. Side effects include nausea, vomiting, diarrhea and abdominal pain. Stomatitis and glossitis have been reported. Other side effects include headache and allergic reactions ranging from urticaria and mild skin rashes.

CONTRAINDICATIONS

It is contraindicated in patients with known hypersensitivity to Clarithromycin or any other macrolide antibiotics.

PRECAUTIONS

Clarithromycin is principally excreted by the liver and kidney. Caution should be exercised in administering this antibiotic to patients with impaired hepatic and renal functions. Prolonged or repeated use of Clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi. If super infection occurs, Clarithromycin should be discontinued and appropriate therapy instituted. Concomitant administration with Theophylline has been associated with increased serum Theophylline level. Effects of Digoxin and Warfarin may be potentiated with concomitant administration with Clarithromycin.

DRUG INTERACTIONS

Clarithromycin should not be prescribed with Terfenadine and Cisapride.

SUPPLY

Tablet 250 : Each box contains 2 x 4 tablets in blister.

Tablet 500 : Each box contains 2 x 4 tablets in blister.

Powder for Suspension : Each carton contains required quantity of powder to prepare 60 ml suspension in glass bottle & a measuring cup.

Store below 30°C & dry place, protected from light.
Keep all medicines out of reach of children.

★ Further information is available on request.

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Manufactured by:

The ACME Laboratories Ltd.

Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness