

# Remac<sup>®</sup>

## Clarithromycin

### COMPOSITION :

Remac<sup>®</sup> 500 tablet : Each tablet contains Clarithromycin EP 500 mg.

### PHARMACOLOGY

Clarithromycin acts by inhibiting microsomal protein synthesis in susceptible organisms mainly by binding to the donor site on the 50S subunit of the bacterial ribosome and preventing translocation to that site. Clarithromycin is active against most Gram-positive bacteria and Chlamydia, some Gram-negative bacteria and Mycoplasmas. Clarithromycin's activity is the same as, or greater than, that of erythromycin in vitro against most Gram-positive bacteria. Clarithromycin is more acid stable than erythromycin and therefore, is better tolerated. Clarithromycin has twice the activity of erythromycin against *H. influenzae*. Most species of Gram-negative bacteria are resistant to clarithromycin because of failure to penetrate to the target.

### INDICATION

Clarithromycin is indicated in-

(1) Streptococcal pharyngitis (2) Sinusitis (3) Infective exacerbations of chronic bronchitis (4) Community-acquired pneumonia (5) Atypical pneumonia (6) Skin and soft tissue infection (7) Adjunct in the treatment of duodenal ulcers by eradication of *H. pylori*

### DOSAGE AND ADMINISTRATION

Clarithromycin may be given with or without meals.

*Adults:*

Infection (every 12 hour)	Dosage	Normal Duration (days)
Pharyngitis/Tonsillitis	250 mg	10
Acute maxillary sinusitis	500 mg	14
Chronic bronchitis	250 - 500 mg	7-14
Pneumonia	250 mg	7-14
Uncomplicated skin and skin structure infections	250 mg	7-14
Community-acquired upper and lower respiratory tract infections	250 - 500 mg	5-14

*Children:*

Body weight under 8 kg	: 7.5 mg/kg twice daily
Body weight of 8-11 kg (1-2 years)	: 62.5 mg twice daily
Body weight of 12-19 kg (3-6 years)	: 125 mg twice daily
Body weight of 20-29 kg (7-9 years)	: 187.5 mg twice daily
Body weight of 30-40 kg (10-12 years)	: 250 mg twice daily

### CONTRAINDICATION AND PRECAUTION

Hypersensitivity to clarithromycin, erythromycin or any of the macrolide antibiotics. Patients receiving terfenadine who have pre-existing cardiac abnormalities or electrolyte disturbances. Clarithromycin is principally excreted by the liver and kidney. Caution should be taken in administering this antibiotic to patients with impaired hepatic and renal function. Prolonged repeated use of clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi. If superinfection occurs, clarithromycin should be discontinued and appropriate therapy should be instituted.

### DRUG INTERACTION

Theophylline: Concomitant use of clarithromycin who are receiving theophylline may be associated with an increase in serum theophylline concentrations.

Terfenadine: Clarithromycin may alter the metabolism of terfenadine.

Carbamazepine : Clarithromycin may increase area under the serum concentration-time curve (AUC) for carbamazepine and decreased peak serum concentration and AUC for carbamazepine.

### USE IN PREGNANCY AND LACTATION

The drug may be used in neonates and children in appropriate doses. Breast milk from mothers receiving clarithromycin should not be given to infants until treatment is completed. There is as yet little experience in treatment of pregnant patients and clarithromycin is not recommended. No special precautions are required for the older patients provided the renal function is not impaired.

### STORAGE

Store below 30°C. Protect from light & moisture.  
Keep out of children's reach.

### HOW SUPPLIED

Remac<sup>®</sup> 500 tablet: Box containing 1 x 10 / 3 x 10 / 5 x 10  
film coated tablets in Alu-PVDC blister pack.

**SQUARE**