Remac®

Clarithromycin USP

COMPOSITION

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

Remac® GFS : After reconstitution each 5 ml contains 125 mg Clarithromycin USP.

PHARMACOLOGY

Clarithromycin acts by inhibiting microsomal protein synthesis in susceptible organisms mainly by binding to the donor site on the 50S sub-unit 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 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 & ADMINISTRATION

Clarithromycin may be given with or without meals.

Adults:

Infection	Dosage (every 12 hour)	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 & 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

ADVERSE EFFECTS

Clarithromycin is generally well tolerated. Side effects include nausea, vomiting, diarrhoea and abdominal pain. Stomatitis and glossitis have also been reported. Other side effects include headache, allergic reactions ranging from urticaria and mild skin reactions to anaphylaxis. Taste perversion may occur. There have been reports of transient central nervous system side effects including anxiety, dizziness, insomnia and hallucination.

PRECAUTION

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 or 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.

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.

CONTRAINDICATION

Hypersensitivity to Clarithromycin, Erythromycin or any of the macrolide antibiotics.

Patients receiving Terfenadine who have pre-existing cardiac abnormalities or electrolyte disturbances.

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.

STORAGE CONDITION

Store in a cool and dry place, protected from light & moisture.

HOW SUPPLIED:

Remac® GFS :Each bottle containing granules to make 60 ml suspension with a measuring cup.

Remac® 500 tablet : Box containing 1 x 6 film coated tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH