

# Rolacin®

Tablet

## Description

Rolacin (Clarithromycin) is a semisynthetic antibiotic of macrolide group, available as 250 mg and 500 mg film coated tablet. It binds to the 50S ribosomal subunit of susceptible bacteria and suppresses its protein synthesis. Rolacin is highly effective against a wide range of aerobic and anaerobic Gram-positive and Gram-negative bacteria. The active ingredient of Rolacin is Clarithromycin USP.

## Indications

Rolacin (Clarithromycin) is indicated for the treatment of mild to moderate infections caused by susceptible strains of the microorganisms listed below :

- ◆ Upper respiratory tract infections : pharyngitis and tonsillitis due to *Streptococcus pyogenes*, Acute maxillary sinusitis due to *Streptococcus pneumoniae*
- ◆ Lower respiratory tract infections : pneumonia due to *Mycoplasma pneumoniae* or *Streptococcus pneumoniae*, Acute exacerbation of chronic bronchitis
- ◆ Uncomplicated skin and skin structure infections due to *Staphylococcus aureus* or *Streptococcus pyogenes*
- ◆ Acute otitis media
- ◆ As an adjunct in the treatment of duodenal ulcers for the eradication of *H. pylori*.

## Dosage and Administration

*Adult* : 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.

In patients with renal impairment with creatinine clearance < 30 ml/ min, the dosage should be reduced by half.

Eradication of *H. pylori* :

Rolacin 500 (Clarithromycin) 1 Tablet twice daily

Proceptin 20 (Omeprazole) 1 Capsule twice daily

Filmet 400 (Metronidazole) 1 Tablet twice daily

(For 7-day treatment regimen)

*Dosage schedule of Children :*

Body weight under 8 kg : 7.5 mg/kg twice daily

8-11 kg (1 to 2 years) : 62.5 mg twice daily

12-19 kg (3 to 6 years) : 125 mg twice daily

20-29 kg (7 to 9 years) : 187.5 mg twice daily

Children older than 10 years : 250 mg twice daily

The usual duration of treatment is 7 to 14 days depending on the pathogen involved and the severity of infection.

### **Contraindication**

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 superinfection 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 of Clarithromycin.

### **Drug Interactions**

Clarithromycin should not be prescribed with Terfenadine and Cisapride.

### **Side Effects**

Rolacin is generally well tolerated. Commonly reported side effects include nausea, vomiting, diarrhoea, abdominal pain, stomatitis and glossitis. Other side effects include allergic reactions and headache.

**Commercial Packs**

Rolacin<sup>®</sup> 250 Tablet : Box containing 20 tablets in 2 x 10's blister strips.  
Each film coated tablet contains Clarithromycin USP 250 mg.

Rolacin<sup>®</sup> 500 Tablet : Box containing 10 tablets in 1 x 10's blister strip.  
Each film coated tablet contains Clarithromycin USP 500 mg.