

## ROVIXIM 200/100 TABLETS & ROVIXIME DRY SYRUP

### COMPOSITION

#### Rovixim 200 DT

Each tablet contains ..... Cefixime 200 mg

#### Rovixim 100 DT

Each tablet contains ..... Cefixime 100 mg

#### Rovixim Dry Syrup

Each 5 ml (after reconstitution) contains .....Cefixime 50 mg.

### INDICATIONS

To reduce the development of drug resistant bacteria and maintain the effectiveness of **ROVIXIM**(cefixime) and other antibacterial drugs, **ROVIXIM** should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

**ROVIXIM** is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms: *Uncomplicated Urinary Tract Infections* caused by *Escherichia coli* and *Proteus mirabilis*.

*Otitis Media* caused by *Haemophilus influenzae* (beta-lactamase positive and negative strains), *Moraxella (Branhamella) catarrhalis*, (most of which are beta-lactamase positive) and *S. pyogenes*\*.

Pharyngitis and Tonsillitis, caused by *S. pyogenes*

Note: Penicillin is the usual drug of choice in the treatment of *S. pyogenes* infections, including the prophylaxis of rheumatic fever. **ROVIXIM** is generally effective in the eradication of *S. pyogenes* from the nasopharynx; however, data establishing the efficacy of **ROVIXIM** in the subsequent prevention of rheumatic fever are not available.

Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis, caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* (beta-lactamase positive and negative strains)

Uncomplicated gonorrhea (cervical/urethral), caused by *Neisseria gonorrhoeae* (penicillinase- and non-penicillinase- producing strains).

Appropriate cultures and susceptibility studies should be performed to determine the causative organism and its susceptibility to cefixime; however, therapy may be started while awaiting the results of these studies. Therapy should be adjusted, if necessary, once these results are known.

\* Efficacy for this organism in this organ system was studied in fewer than 10 infections

### DOSAGE AND ADMINISTRATION

**Adults:** The recommended dose of cefixime is 400 mg daily. This may be given as a 400 mg tablet daily or as 200 mg tablet every 12 hours. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended.

**Children:** The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.

Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose. Otitis media should be treated with the suspension. Clinical studies of otitis media were conducted with the suspension, and the suspension results in higher peak blood levels than the tablet when administered at the same dose. Therefore, the tablet should not be substituted for the suspension in the treatment of otitis media. Efficacy and safety in infants aged less than six months have not been established. In the treatment of infections due to *S. pyogenes*, a therapeutic dosage of **ROVIXIM** should be administered for at least 10 days.

### Renal Impairment

**ROVIXIM** may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. Patients whose clearance is between 21 and 60 mL/min or patients who are on renal hemodialysis may be given 75% of the standard dosage at the standard dosing interval (i.e., 300 mg daily). Patients whose clearance is < 20 mL/min or patients who are on continuous ambulatory peritoneal dialysis may be given half the standard dosage at the standard dosing interval (i.e., 200 mg daily). Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

### CONTRAINDICATIONS

**ROVIXIM** is contraindicated in patients with known allergy to the cephalosporin or ofloxacin or any member of the quinolone group of antibiotics.

### PACKAGING INFORMATION

**Rovixim 200DT Tablets** ..... Alu-ALu Pack of 10 tablets  
**Rovixim 100DT Tablets** ..... Alu-ALu Pack of 10 tablets  
**Rovixim Dry Syrup** ..... Bottle of 30 ml