

Y.S.P.

CUT25 PHL-001  
R.O.C. Reg. No.:045671

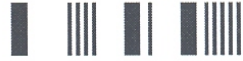
# CEFUROXIME AXETIL



## ROMICEF

250 mg Film-Coated Tablet

### ANTIBACTERIAL



**FORMULATION:**

Each film-coated tablet contains:

Cefuroxime (as axetil) .....250 mg

**ACTIONS:**

1. Cefuroxime has in vitro activity against a wide range of gram-positive and gram-negative organisms, and it is highly stable in the presence of  $\beta$ -lactamases of certain gram-negative bacteria. It is more active against many of the Enterobacteriaceae including some strains of Enterobacter, E. coli, Klebsiella and Salmonella spp. and Indole positive Proteus spp.
2. Cefuroxime axetil is absorbed from the gastro-intestinal tract and is rapidly hydrolysed in the intestinal mucosa and blood to cefuroxime. The absorption is enhanced in the presence of food.
3. Peak plasma concentrations are reported about 2 to 3 hours after an oral dose. Up to 50% of Cefuroxime is bound to plasma proteins. The plasma half-life is about 70 minutes and is prolonged in patients with renal impairment and in neonates.
4. Cefuroxime is widely distributed in the body including pleural fluid, sputum, bone, synovial fluid, and aqueous humour, but only achieves therapeutic concentrations in the CSF when the meninges are inflamed. It crosses the placenta and has been detected in breast milk.
5. Cefuroxime is excreted unchanged, by glomerular filtration and renal tubular secretion, and high concentrations are achieved in the urine.

**INDICATION:**

For the treatment of infections caused by staphylococci, streptococci, pneumococci, meningococci, and other susceptible microorganisms.

**DOSAGE AND ADMINISTRATION:**

Usual adult dose is 250 to 500 mg twice daily for respiratory tract infections; 125 mg twice daily for uncomplicated urinary tract infections. In pyelonephritis the recommended dose is 250 mg twice a day. A single dose of 1 gram is recommended for uncomplicated gonorrhoea. Children: Usual dose is 125 mg twice daily for children more than 3 months of age or 10 mg per kg body weight twice daily to a maximum of 250 mg daily. Children over 2 years of age with otitis media may be given 250 mg twice daily or 15 mg per kg twice daily to a maximum of 500 mg daily.

**CONTRAINDICATION:**

Contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

**PRECAUTION:\***

1. Cefuroxime should be given with caution to patients receiving concurrent administration with potent diuretics and to patients with renal impairment.
2. The total daily dose of Cefuroxime should be reduced in patients with impaired renal function.
3. Cefuroxime should be given with caution in patients with a history of gastro-intestinal disease, particularly colitis.
4. Cefuroxime may cause false-negative reactions in the ferricyanide test for blood glucose.
5. There are no adequate and well-controlled studies in pregnant women. The drug should be used during pregnancy only if clearly needed.

**ADVERSE REACTION:**

Gastro-intestinal disturbances, including diarrhea, nausea and vomiting have occurred in some patients. There have been rare reports of erythema multiforme, including the Stevens-Johnson syndrome, and toxic epidermal necrolysis.

**CAUTION:**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**STORAGE CONDITION:**

Store at a temperature not exceeding 30°C. Protect from light and moisture.

**AVAILABILITY:**

Blister pack of 10 x 10 (Box of 100 )



Manufactured by:  
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