

Brocef^{Tablet}

Cefuroxime 250 & 500 mg

PRESENTATION:

Brocef 250 Tablet: Each film coated tablet contains 250 mg of Cefuroxime as Cefuroxime Axetil USP.

Brocef 500 Tablet: Each film coated tablet contains 500 mg of Cefuroxime as Cefuroxime Axetil USP

DESCRIPTION:

Cefuroxime (Brocef) is a broad-spectrum second generation Cephalosporin which is active against both gram (+)ve & gram (-)ve aerobes and anerobes. It has bactericidal activity against a wide range of common pathogens including beta-lactamase producing strains. Consequently Cefuroxime kills bacteria interfering the synthesis of bacterial cell wall by inhibiting the transpeptidase enzyme.

PHARMACOKINETICS:

After oral administration Cefuroxime Axetil is absorbed from the gastrointestinal tract and rapidly hydrolysed to Cefuroxime by nonspecific esterases in the intestinal mucosa and blood. Cefuroxime is subsequently distributed throughout the extracellular fluids. The Axetil moiety is metabolised to acetaldehyde and acetic acid. It is approx 50% protein bound & the half-life is 1.2 hours. Absorption is greater when taken after food. The drug is excreted unchanged in the urine within 12 hours. As Cefuroxime is renally excreted, the serum half-life is prolonged in patients with reduced renal function. Despite the lower elimination of Cefuroxime in geriatric patients, dosage adjustment based on age is not necessary.

INDICATIONS:

Cefuroxime Axetil (Brocef) is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

***Pharyngitis/Tonsillitis** caused by *Streptococcus pyogenes*

***Acute bacterial otitis media** caused by *S. pneumoniae*, *H. influenzae* (including beta-lactamase producing strains), *M. catarrhalis* (including beta-lactamase producing strains) or *S. pyogenes*.

***Acute bacterial maxillary sinusitis** caused by *S. pneumoniae* or *H. influenzae* (non-beta-lactamase producing strains only)

***Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis** caused by *S. pneumoniae*, *H. influenzae* (beta-lactamase negative strains), or *H. parainfluenzae* (beta-lactamase negative strains)
"Uncomplicated skin and skin-structure infections caused by *S. aureus* (Including beta-lactamase producing strains), or *S. pyogenes*.

***Uncomplicated urinary tract infections** caused by *E. coli* or *K. pneumoniae*

***Uncomplicated gonorrhoea, urethral and endocervical infections** caused by penicillinase producing and non-penicillinase producing strains of *N. gonorrhoeae* and uncomplicated rectal gonorrhoea in females caused by non-penicillinase producing strains of *N. gonorrhoeae*

***Early Lyme disease (Erythema migrans)** caused by *Borrelia burgdorferi*.

***Obstetric and gynaecological infection** pelvic inflammatory diseases.

* **Other infections** including septicemia and meningitis.

DOSAGE AND ADMINISTRATION

Oral: Cefuroxime Axetil (Brocef) should be taken after food for optimum absorption.

| Population | Infections | Dosage | Duration (days) |
|---|---|-------------------|-----------------|
| Adolescents and Adults (13 years and older) | Pharyngitis/Tonsillitis | 250 mg bid | 10 |
| | Acute bacterial maxillary sinusitis | 250 mg bid | 10 |
| | Acute bacterial exacerbations of chronic bronchitis | 250 or 500 mg bid | 10 |
| | Secondary bacterial infections of acute bronchitis | 250 or 500 mg bid | 5-10 |
| | Uncomplicated skin and skin structure infections | 250 or 500 mg bid | 10 |
| | Uncomplicated urinary tract infections | 125 or 250 mg bid | 7-10 |
| | Uncomplicated gonorrhea | 1000 mg once | Single dose |
| | Early Lyme Disease | 500 mg bid | 20 |
| Paediatric (who can swallow tablet) | Pharyngitis/Tonsillitis | 125 mg bid | 10 |
| | Acute otitis media | 250 mg bid | 10 |
| | Acute bacterial maxillary sinusitis | 250 mg bid | 10 |

SIDE EFFECTS:

Generally cefuroxime is well tolerated. However, a few side effects like nausea, vomiting, diarrhoea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of cefuroxime may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.20%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

CONTRAINDICATIONS:

It is contraindicated in patients with known hypersensitivity to the cephalosporin group of antibiotics.

PRECAUTIONS:

Penicillin sensitivity; renal impairment, pregnancy & breast-feeding: false positive urinary glucose & false positive-Coomb's test

PREGNANCY & LACTATION:

Because cefuroxime is excreted in human milk, consideration should be given during treatment with cefuroxime

DRUG INTERACTIONS:

Probenecid increases cefuroxime blood levels; drugs lowering gastric acidity may decrease cefuroxime bioavailability

STORAGE:

Do not store above 30° C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING:

Brocef 500 Tablet: Each box contains 1x7's tablets in Alu-Alu blister pack.

Brocef 250 Tablet: Each box contains 2x7's tablets in Alu-Alu blister pack.

Manufactured by:
Gaceo Pharmaceuticals
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