

PRESENTATION:

**Brocef-CV 500 Tablet:** Each film coated tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.

**Brocef-CV 250 Tablet:** Each film coated tablet contains Cefuroxime 250 mg as Cefuroxime Axetil USP and Clavulanic Acid 62.5 mg as diluted Potassium Clavulanate BP.

DESCRIPTION:

Cefuroxime 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. It is Indicated for the treatment of infections caused by sensitive bacteria.

Clavulanic acid has a similar structure to the beta-lactam antibiotics but binds irreversibly to the beta-lactamase enzymes and inactivates them. Clavulanic acid in Brocef-CV gives protection of Cefuroxime from degradation by beta-lactamase enzyme and provides a solution for treatment of bacterial infections caused by beta lactam resistant pathogens.

INDICATIONS AND USES:

\*Acute Bacterial Exacerbations of Chronic Bronchitis and Secondary Bacterial Infections of Acute Bronchitis caused by ***Streptococcus pneumoniae, Haemophilus influenzae*** (beta-lactamase negative strains), or ***Haemophilus parainfluenzae*** (beta-lactamase negative strains)

\*Acute Bacterial Otitis Media caused by ***Streptococcus pneumoniae, Haemophilus influenzae*** (including beta-lactamase-producing strains), ***Moraxella catarrhalis*** (including beta-lactamase-producing strains), or ***Streptococcus pyogenes***.

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

\*Skin and Skin-Structure infections caused by ***Staphylococcus aureus*** (penicillinase-and non-penicillinase-producing strains), ***Streptococcus pyogenes, Escherichia coli, Klebsiella spp and Enterobacter spp***

\*Acute bacterial Maxillary Sinusitis caused by ***Streptococcus pneumoniae or Haemophilus influenzae*** (non-beta-lactamase-producing strains only)

\*Urinary Tract Infections caused by ***Escherichia*** coil or ***Klebsiella pneumoniae***.

\*Gonorrhea: Uncomplicated and disseminated-gonococcol infections due to Neiseria

gonorrhoeae (penicillinase-and non-penicillinase-producing strains) in both males and females.

\*Impetigo caused by ***Staphylococcus aureus*** (including beta-lactamase-producing strains) or ***Staphylococcus pyogenes***.

\*Switch therapy (injectable to oral) after surgery when patients condition is improved.

\*Early Lyme disease (erythema migrans) caused by ***Borrelia burgdorferi***

DOSAGE AND ADMINISTRATION

Brocef-CV should be taken after food for optimum absorption.

| Population  | Infections  | Dosage                           | Duration (days) |
|---|---|----------------------------------|-----------------|
| Adolescents and Adults<br>(13 years and older)        | Pharyngitis/Tonsillitis                             | 250 mg bid daily                 | 10              |
|   | Acute bacterial maxillary sinusitis                 | 250 mg bid daily                 | 10              |
|   | Acute bacterial exacerbations of chronic bronchitis | 250 mg bid daily                 | 10              |
|   | Secondary bacterial infections of acute bronchitis  | 250 or 500 mg bid daily          | 5-10            |
|   | Uncomplicated skin and skin structure infections    | 250 or 500 mg bid daily          | 10              |
|   | Uncomplicated urinary tract infections              | 250 mg bid daily                 | 7-10            |
|   | Uncomplicated gonorrhea                             | 1000 mg once daily               | Single dose     |
|   | Early Lyme Disease                                  | 500 mg bid daily                 | 20              |
| Paediatric Patients<br>(who can swallow tablet Whole) | Pharyngitis/Tonsillitis                             | 125 mg bid daily                 | 10              |
|   | Acute otitis media                                  | 250 mg bid                       | 10              |
|   | Acute bacterial maxillary sinusitis                 | 250 mg bid                       | 10              |
| Paediatric Patient<br>(3 months to 12 years)          | Pharyngitis/Tonsillitis                             | 20 mg/kg/day in two divided dose | 10              |
|   | Acute otitis media                                  | 30 mg/kg/day in two divided dose | 10              |
|   | Acute bacterial maxillary sinusitis                 | 30 mg/kg/day in two divided dose | 10              |
|   | Impetigo  | 30 mg/kg/day in two divided dose |                 |

SIDE EFFECTS:

Generally cefuroxime and clavulanic acid are 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 & Clavulanic acid combination may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.20%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

PRECAUTIONS:

Brocef-CV should be given with care to patients receiving concurrent treatment with potent diuretics and who have history of colitis.

USE IN PREGNANCY & LACTATION:

**During Pregnancy:** While all antibiotics should be avoided in the first trimester if possible, however Brocef-CV can be safely used in later pregnancy to treat urinary and other infections.

**During lactation:** Because Brocef-CV is acceptable to use during breast feeding as it is excreted in small quantities into breast milk. However, the possibility of sensitizing the infant should be kept in mind.

CONTRAINDICATIONS:

Patients with Known hypersensitivity to Cephalosporins & Pseudomembraneous colitis are contraindicated.

STORAGE:

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

PACKAGING:

**Brocef-CV 500 Tablet:** Each box contains 1x8's tablets in Alu-Alu blister pack.

**Brocef-CV 250 Tablet:** Each box contains 1x10's tablets in Alu-Alu blister pack.