Furoclav®

(Cefuroxime + Clavulanic Acid)

Presentation

Furoclav® 125 : Each film coated tablet contains Cefuroxime 125mg as Cefuroxime Axetil BP and Clavulanic Acid 31.25mg as diluted Potassium Clavulanate BP.

Furoclav® 250 : Each film coated tablet contains Cefuroxime 250mg as Cefuroxime Axetil BP and Clavulanic Acid 62.5 mg as diluted Potassium Clavulanate BP.

Furoclav® 500 : Each film coated tablet contains Cefuroxime 500mg as Cefuroxime Axetil BP and Clavulanic Acid 125mg as diluted Potassium Clavulanate BP.

Furoclav® Powder for Suspension: Each 5ml suspension contains Cefuroxime 125mg as Cefuroxime Axetil BP and Clavulanic Acid 31.25mg as diluted Potassium Clavulanate BP.

Description

Cefuroxime has bactericidal activity against a wide range of common pathogens, including beta-lactamase producing strains. The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins. Cefuroxime has good stability to bacterial beta-lactamases. Clavulanic acid is a naturally derived beta lactamase inhibitor produced by Streptomyces clavuligerus. Clavulanic acid binds to and inactivates them thus preventing the destruction of cefuroxime that is a substrate for this enzyme. It has poor intrinsic antimicrobial activity, but it is an irreversible binder of ß-lactamases produced by a wide range of gram positive and gram negative microorganism.

Rationale for combination

Although Clavulanic acid does have some degree of bacterial activity, its principal role is as a beta-lactamase inhibitor. β-lactam antibiotics, such as the penicillins and cephalosporins, act by disrupting the development of bacterial cells walls thus causing the disintegration of the bacteria. However, some bacteria acquire the genes to produce enzymes which inactivate this mode of action - so called β-lactamases - drastically reducing the efficacy of this class of antibiotics.

Clavulanic acid has a similar structure to the beta-lactam antibiotics but binds irreversibly to the beta-lactamase enzymes. Used in combination with the beta-lactam antibiotics, it has become one of the most prescribed antibiotics prolonging the effective life of antibiotics. Thus, the combination of cefuroxime and clavulanic acid (β-lactamase inhibitor) provides a solution for treatment of bacterial infections caused by beta lactam resistant pathogens.

INDICATIONS

Furoclav® 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 *Streptococcus pneumoniae, Haemophilus influenzae* (including beta-lactamase–producing strains), *Moraxella catarrhalis* (including beta-lactamase–producing strains), or *Streptococcus pyogenes*.

Acute Bacterial Maxillary Sinusitis caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (non-β-lactamase–producing strains only).

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

Uncomplicated Skin and Skin-Structure Infections caused by *Staphylococcus aureus* (including β-lactamase–producing strains) or *Streptococcus pyogenes*.

Uncomplicated Urinary Tract Infections caused by *Escherichia coli* or *Klebsiella pneumoniae*.

Uncomplicated Gonorrhea, (urethral and endocervical) caused by penicillinase-producing and non-penicillinase–producing strains of *Neisseria gonorrhoeae*.

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

Furoclav® Suspension: Suspension may be administered to pediatric patients ranging in age from 3 months to 12 years, according to dosages in Table 2.

TABLE 2: Indications & dosage for Furoclav Oral Suspension (Must be administered with food. Shake well each time before using.)

Population/Infection	Dosage	Daily Maximum Dose	Duration (days)
Pediatric Patients (3 months to 12 years)			
Pharyngitis/tonsillitis	20 mg/kg/day divided b.i.d.	500mg	10
Acute otitis media	30 mg/kg/day divided b.i.d.	1,000mg	10
Acute bacterial maxillary sinusitis	30 mg/kg/day divided b.i.d.	1,000 mg	10
Impetigo	30 mg/kg/day divided b.i.d.	1,000 mg	10

ADVERSE EFFECTS

Generally Cefuroxime and Clavulanic acid are well tolerated. Adverse reactions to cefuroxime axetil have been generally mild and transient in nature. The following adverse reactions to cefuroxime axetil have been reported.

• Major adverse reactions which may occur are diarrhea/loose motions, nausea/vomiting, transient elevation in AST, ALT, LDH, Eosinophilia.

• Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.

PRECAUTIONS

Cefuroxime and Clavulanic acid combination should be given with caution to patients receiving potent diuretics and who have a history of colitis.

Use in pregnancy & lactation

During pregnancy: While all antibiotics should be avoided in the first trimester if possible. However, Furoclav can be safely used in later pregnancy to treat urinary and other infections.

During lactation: Because Cefuroxime-clav is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime.

DRUG INTERACTIONS

Probenecid: Concomitant administration of probenecid with cefuroxime axetil tablets increases the area under the serum concentration versus time curve by 50%.

Antacids: Drugs that reduce gastric acidity may result in a lower bioavailability of CEFUROXIME-CLAV compared with that of fasting state and tend to cancel the effect of postprandial absorption.

Overdoasge

Overdosage can cause cerebral irritation leading to convulsions. In this case, serum levels can be reduced by hemodialysis and peritoneal dialysis.

Storage Condition

Furoclav® tablets and suspension should be kept in a cool (15° - 30°) and dry place and protected from light.

Commercial pack

Furoclav® 125 : Each box contains 2 alu-alu blister strips of 6 tablets.

Furoclav® 250 : Each box contains 2 alu-alu blister strips of 7 tablets.

Furoclav® 500 : Each box contains 2 alu-alu blister strips of 7 tablets.

Furoclav® Powder for Suspension : After reconstitution, each phial will contain 70ml suspension having Cefuroxime 125mg and clavulanic acid 31.25mg per 5 ml.

Manufactured by
RENATA LIMITED
Rajendrapur, Gazipur, Bangladesh
®Trademark

Updated: May, 2017
C-Code : 105213497/V02