KefuClav®

Cefuroxime & Clavulanic Acid Film Coated Tablet & Powder for Suspension

DESCRIPTION

KefuClav® is a combined preparation of Cefuroxime & Clavulanic Acid. 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.

INDICATIONS

- **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-beta-lactamase-producing strains only).
- **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).
- **Uncomplicated Skin and Skin-Structure Infections:** caused by *Staphylococcus aureus* (including beta-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 & non-penicillinase producing strains of *Neisseria gonorrhoeae* and uncomplicated gonorrhea, rectal, in females, caused by non-penicillinase-producing strains of *Neisseria gonorrhoeae*.
- **Early Lyme disease (erythema migrans):** caused by *Borrelia burgdorferi*.
- **Impetigo:** caused by *Staphylococcus aureus* (including beta-lactamase-producing strains) or *Streptococcus pyogenes*.

DOSAGE AND ADMINISTRATION

Tablet

Oral: Adolescents & Adults (13 years & older)

Infection	Dosage	Duration (days)
Pharyngitis/tonsillitis	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10
Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg b.i.d.	10
Secondary bacterial infections of acute bronchitis	250 or 500 mg b.i.d.	05-10
Uncomplicated skin and skin-structure infections	250 or 500 mg b.i.d.	10
Uncomplicated urinary tract infections	250 mg b.i.d.	07-10
Uncomplicated gonorrhea	1,000 mg once	single dose
Early Lyme disease	500 mg b.i.d.	20

Oral: Paediatric patients (who can swallow tablet)

Infection	Dosage	Duration (days)
Acute otitis media	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10

Suspension

Oral: Paediatric Patients (3 months to 12 years):

Infection	Dosage	Daily Maximum Dose	Duration (days)
Pharyngitis/tonsillitis	20 mg/kg/day divided b.i.d.	500 mg	10
Acute otitis media	30 mg/kg/day divided b.i.d.	1,000 mg	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

CONTRAINDICATIONS

It is contraindicated in patients with a known hypersensitivity to Cephalosporin group of antibiotics and Clavulanic Acid.

USE IN PREGNANCY AND LACTATION

No adequate and well-controlled studies in pregnant women have been reported, so **KefuClav®** should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician. Because Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime.

PRECAUTIONS AND WARNINGS

- Before therapy with **KefuClav®** is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to Cephalosporins, Penicillins or other drugs.
- Prescribing **KefuClav®** in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
- Cephalosporins, including Cefuroxime, should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function.
- Cefuroxime, as with other broad-spectrum antibiotics, should be prescribed with caution in individuals with a history of colitis.

SIDE EFFECTS

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

PHARMACEUTICAL PRECAUTIONS

Tablet : Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

Powder for Suspension : Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children. Reconstituted suspension should be kept tightly closed and stored in a refrigerator (2- 8 °C temperature). Unused portion should be discarded after 7 days.

PACKAGING

KefuClav® 250 Tablet : Box containing 2 strips of 7 tablets or 2 strips of 8 tablets or 10 strips of 8 tablets each. Each Film Coated tablet contains Amorphous Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg & Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 62.5 mg.

KefuClav® 500 Tablet : Box containing 1 strip of 7 tablets or 1 strip of 8 tablets or 1 strip of 10 tablets or 10 strips of 8 tablets each. Each Film Coated tablet contains Amorphous Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg & Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

KefuClav® Powder for Suspension : Bottle containing powder for the preparation of 70 mL suspension. After reconstitution, each 5 mL suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg & Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
® REGD.TRADEMARK
PM03211 V04