SUMMARY PRODUCT CHARACTERISTICS (SPC)

1.1 Name of medicinal product

Cefuroxime with Potassium Clavulanate Tablets

1.2 Strength

Cefuroxime Axetil BP Eq. to Cefuroxime……500 mg

Diluted Potassium Clavulanate BP Eq. to Clavulanic acid … 125 mg

1.3 Pharmaceutical Dosage form

Film coated tablet (For oral administration)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Cefuroxime Axetil BP Eq. to Cefuroxime……500 mg

Diluted Potassium Clavulanate BP Eq. to Clavulanic acid … 125 mg

Color: Sunset Yellow FCF and Titanium dioxide BP

3. PHARMACEUTICAL FORM

Tablet

Orange colored, oblong, biconvex film coated tablet both sides plain.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefuroxime Axetil with Clavulanic acid is indicated for the treatment of:

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).

Lower respiratory tract infections including pneumoniae, caused by Streptococcus pneumoniae, Haemophilus influenzae (including beta lactamase-producing strains), Klebsiella spp., Staphylococcus aureus (penicillinase- and non-penicillinase-producing strains), Streptococcus pyogenes, Escherichia coli.

Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis caused by Streptococcus pneumonia, Haemophilus influenzae (beta-lactamase negative strains) or Haemophilus parainfluenzae (beta-lactamase negative strains). Skin and Skin-Structure Infections caused by Staphylococcus aureus (penicillinase- and non-penicillinase-producing strains), Streptococcus pyogenes, Escherichia coli, Klebsiella spp. and Enterobacter spp. Urinary tract infections caused by Escherichia coli or Klebsiella pneumoniae. Bone and Joint Infections caused by Staphylococcus aureus (penicillinase and non-penicillinase producing strains).

Gonorrhea: Uncomplicated and disseminated gonococcal infections due to Neisseria gonorrhoeae (penicillinase- and non-penicillinase-producing strains) in both males and females.

Early Lyme disease (erythema migrans) caused by Borrelia burgdorferi Septicemia caused by Staphylococcus aureus (penicillinase and non-penicillinase producing strains), Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae (including ampicillin-resistant strains), and Klebsiella spp. Meningitis caused by Streptococcus pneumoniae, Haemophilus influenzae (including ampicillin resistant strains), Neisseria meningitidis and Staphylococcus aureus (penicillinase and non-penicillinase producing strains).

4.2 Posology and method of administration

Adolescents & adults:

Pharyngitis or Tonsillitis: 250 mg twice daily 5-10 days

Acute bacterial maxillary sinusitis: 250 mg twice daily 10 days

Acute bacterial exacerbation of chronic bronchitis: 250-500 mg twice daily 10 days

Secondary bacterial infections of acute bronchitis: 250-500 mg twice daily 5-10 days

Community acquired pneumonia: 250-500 mg twice daily 5-10 days
Uncomplicated skin & skin-structure infections: 250-500 mg twice daily 10 days
MDR Typhoid fever: 500 mg twice daily 10-14 days
Uncomplicated urinary tract infection: 250 mg twice daily 7-10 days
Uncomplicated gonorrhea: 1000 mg single dose
Lyme disease: 500 mg twice daily 20 days

Pediatric patients (3 months to 12 years)
Pharyngitis or Tonsillitis: 20 mg/kg/day in two divided doses 5-10 days
Acute otitis media: 30 mg/kg/day in two divided doses 10 days
Acute bacterial maxillary sinusitis: 30 mg/kg/day in two divided doses 10 days
Community acquired pneumonia: 30 mg/kg/day in two divided doses 5-10 days
MDR Typhoid fever: 30 mg/kg/day in two divided doses 10-14 days
Uncomplicated skin & skin-structure infections: 30 mg/kg/day in two divided doses 10 days
Uncomplicated urinary tract infection: 20 mg/kg/day in two divided doses 7-10 days

Mode of administration
Cefuroxime with Potassium Clavulanate Tablets may be administered without regard to meals.

4.3 Contraindications

Patients with known allergy to cephalosporins & pseudomembranous colitis are contraindicated.

4.4 Special warnings and special precautions for use

Generally, Cefuroxime and Clavulanic acid are well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime and Clavulanic acid combination may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Cefuroxime with Potassium Clavulanate Tablets should be given with care to patients receiving concurrent treatment with potent diuretics & who have history of colitis.

4.5 Interaction with other medicinal products and other forms of Interaction

Concomitant administration of probenecid with Cefuroxime with Potassium Clavulanate Tablets increases the area under the serum concentration versus time curve by 50%. Drug that reduces gastric acidity may result in a lower bioavailability of Cefuroxime and tend to cancel the effect of postprandial absorption.

4.6 Effects on ability to drive and use machines

There are no studies of the effect of cefuroxime and clavulanate on the ability to drive and to handle machines. However, any effects are not to be expected.

4.7 Undesirable effects

Adverse reactions to Cefuroxime Axetil have been generally mild and transient in nature. The following adverse reactions to Cefuroxime Axetil have been reported. However, the possibility of the occurrence of other adverse reactions, seen with the cephalosporin class of antibiotics, should be borne in mind.

Cefuroxime and Clavulanic acid combination may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

After oral administration cefuroxime axetil is absorbed from the gastrointestinal tract and rapidly hydrolyzed in the body to release cefuroxime into the circulation. Approximately 60% of an administered dose is absorbed. Optimum absorption occurs when it is administered after a light meal. Absorption is not decreased by drugs which affect gastrointestinal motility e.g. loperamide, diphenoxylate or castor oil. However, absorption is decreased by concurrent administration of drugs such as ranitidine.

The mean peak serum level of cefuroxime following a 250 mg dose in normal healthy adults, after food, was 4.1 mg/L and occurred two to three hours after dosing. Serum levels were significantly higher in the elderly, apparently due to slower excretion. Unhydrolysed drug was not detected in the serum but 1-2% of the administered dose is excreted in the urine in a form which indicates that small amounts of the intact ester are absorbed into circulation. The mean serum half-life of cefuroxime is approximately 1.2 hours. Protein binding has been variously stated as 33-50% depending on the methodology used. Cefuroxime is not metabolized to any significant extent.

Excretion occurs mainly through the kidney both by glomerular filtration and tubular secretion. Approximately 49% of an administered dose, after food, is recovered in the urine in 24 hours; urinary recovery is significantly reduced if the drug is taken on an empty stomach.

After 250 mg dose urinary concentrations at 0-6 and 6-12 hours were 227 mcg/mL (range 92-515) and 35.3 mcg/mL (range 7.6-102) respectively.

Concurrent administration of probenecid prolongs the terminal half-life of cefuroxime. Serum levels of cefuroxime are reduced by hemodialysis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Sodium Lauryl Sulphate BP
- Polacrilin Potassium USP
- Colloidal Silicon Dioxide BP
- Microcrystalline Cellulose BP
- Magnesium Stearate BP
- Croscarmellose Sodium BP
- Purified Talc BP
- Colour Colorezy 17K580002 INH
- Isopropyl Alcohol BP
- Dichloromethane BP
- Diethyl phthalate BP
- Ethyl Cellulose BP
- Colour Lake Sunset Yellow INH

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25°C, Protected from light and moisture.

6.5 Nature and contents of container

10 tablets per Alu-Alu blister. 1 blister strip in a carton along with package insert.

6.6 Special precautions for disposal

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

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8. Manufacturer

M/s. Finecure Pharmaceuticals Limited,
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9. Date of revision of the text

Not applicable