# CEFUREX®

(Cefuroxime Axetil)

## PROPERTIES

**Cefurex®** (cefuroxime axetil) is a second generation cephalosporin antibiotic which has broad spectrum bactericidal activity by inhibition of cell wall synthesis.

Cefuroxime axetil is resistant to most beta-lactamases and is active against a wide range of gram-positive and gram-negative organisms and against bacterial (ampicillin or amoxicillin) resistant strains.

After oral administration, cefuroxime axetil is absorbed from the gastrointestinal tract and rapidly hydrolyzed in the intestinal mucosa and blood to release cefuroxime into the circulation. Optimum absorption occurs when it is administered after a meal. Peak serum cefuroxime levels occur approximately two to three hours after oral dosing. The serum half life is about 1- 2 hours. Approximately 50% of serum cefuroxime is protein bound. Cefuroxime is not metabolized and is excreted by glomerular filtration and tubular secretion.

Cefuroxime axetil is usually active against the following organisms in vitro:

**Aerobes, Gram-negative:** *Haemophilus influenzae* (including ampicillin resistant strains), *Haemophilus parainfluenzae, Moraxella catarrhalis, Escherichia coli, Klebsiella* species, *Proteus mirabilis, Proteus inconstans, Providencia rettgeri* and *Neisseria gonorrhoeae* (including penicillinase – and non- penicillinase – producing strains).

Some strains of *Morganella morganii, Enterobacter* species and *Citrobacter* species have been shown by in vitro tests to be resistant to cefuroxime axetil and other beta-lactam antibiotics.

**Aerobes, Gram- positive:** *Staphylococcus aureus* (including penicillinase- producing strains, but excluding methicillin- resistant strains), *Staphylococcus epidermidis, Streptococcus pneumoniae* (and other beta-haemolytic streptococci), *Streptococcus* Group B (*Streptococcus agalactiae*) and *Propionibacterium* species. Certain strains enterococci, eg. *Streptococcus faecalis*, are resistant.

**Anaerobes, Gram-positive and Gram-negative cocci** (including *Peptococcus* and *Peptostreptococcus* species). **Gram –positive bacilli** (including *Clostridium* species) and **Gram-negative bacilli** (including *Bacteroides* and *Fusobacterium* species). Most strains of *Bacteroides fragilis* are resistant.

*Pseudomonas* species, *Campylobacter* species, *Acinetobacter calcoaceticus* and most strains of *Serratia* and *Proteus vulgaris* and *Clostridium difficile* are resistant to many cephalosporins including cefuroxime axetil.

## INDICATIONS

**Cefurex®** is indicated in the treatment of many infections including:

-**Lower respiratory tract infections** like acute and chronic bronchitis and pneumonia.

-**Upper respiratory tract infections**: ear, nose and throat infections like otitis media, sinusitis, tonsillitis and pharyngitis.

-**Genito- urinary tract infections** like acute and chronic pyelonephritis, cystitis and urethritis.

-**Skin and soft tissue infections** like furunculosis, pyoderma and impetigo.

-**Gonorrhea:** acute uncomplicated gonococcal urethritis and cervicitis.

## SIDE EFFECTS

Adverse reactions to cefuroxime axetil have occurred relatively infrequently and have been generally mild and transient in nature. Effects reported include:

- Gastrointestinal disturbances as nausea, diarrhea and vomiting.

-Pseudo-membranous colitis has been rarely reported with cefuroxime axetil, as with all other broad spectrum antibiotics.

-Headache has been reported.

-There have been rare reports of hypersensitivity reactions, including skin rashes.

-Eosinophilia and transient increases of hepatic enzyme levels, ALT (SGPT) and AST (SGOT) have been noted.

-A false positive comb's test has been reported in some patients during treatment with cefuroxime axetil.

## CONTRAINDICATIONS

Cefuroxime axetil is contraindicated for patients with known hypersensitivity to cephalosporins.

## PRECAUTIONS

Although cross-reactions have been reported between penicillins and cephalosporins, but like all other cephalosporin antibiotics, cefuroxime axetil can be given safely to patients who are hypersensitive to penicillins, and a special care is indicated in patients who have experienced an anaphylactic reaction to penicillins.

As with other antibiotics, prolonged use of cefuroxime axetil may result in the overgrowth of non-susceptible organisms (e.g. Candida, Enterococci and Clostridium difficile) which may require interruption of the treatment.

Pseudo-membranous colitis has been reported with the use of broad-spectrum antibiotics; therefore, it is important to consider its diagnosis in patients who develop serious diarrhea during or after antibiotics use.

Cefuroxime axetil tablets should not be crushed and are, therefore, unsuitable for children under the age of five years.

It is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving cefuroxime axetil. This antibiotic does not interfere with the alkaline picrate assay for creatinine.

False positive reactions for urine glucose tests may occur in patients receiving cefuroxime axetil if using methods depending on copper reduction, e.g. Fehling's, Benedict's, Clinitest, so it is recommended in this case to use the enzyme-based tests for this test.

## PREGNANCY AND LACTATION

Pregnancy category B.

There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime axetil but, as with all drugs, it should be administered with caution during the early months of pregnancy. Cefuroxime axetil is excreted in the human milk, and consequently caution should be exercised when it is administered to a nursing mother.

## DRUG-DRUG INTERACTIONS

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

The peak serum cefuroxime concentration after 1.5 g single dose is greater when taken with 1 g of probenecid (mean =14.8 mcg/ml) than without probenecid (mean =12.2 mcg/ml).

## OVERDOSAGE

Overdose may cause cerebral irritancy leading to convulsions. Serum levels of cefuroxime are reduced by peritoneal dialysis or haemodialysis.

## DOSAGE AND ADMINISTRATION

**Adults:**

-In mild to moderate lower respiratory tract infections, the infections will respond to 250mg twice daily. In severe infections e.g. (pneumonia) the dose may be raised to 500mg twice daily.

-In uncomplicated gonorrhea, 1g should be given as a single dose.

-In urinary tract infections, 125mg should be given twice daily, in pyelonephritis the recommended dose is 250mg twice daily.

-In skin and soft tissue infections, the recommended dose is 250mg twice daily and may be raised to 500mg twice daily.

**Children:**

-The usual dose is 125mg twice daily. In children with otitis media, the usual dose is 125 mg twice daily in children less than 2 years of age and 250 mg twice daily in children over 2 years of age. There is no adequate experience in children under 3 months of age.

No special precautions are necessary in patients with renal impairment or on renal dialysis or in the elderly at dosages up to the normal maximum of 1 g per day.

Cefuroxime axetil should be taken after food for optimum absorption.

## PRESENTATIONS

**Cefurex®** 125 tablets, each film coated tablet contains 125mg cefuroxime axetil U.S.P. in a pack of 10 tablets.

**Cefurex®** 250 tablets, each film coated tablet contains 250mg cefuroxime axetil U.S.P. in a pack of 10 tablets.

**Cefurex®** 500 tablets, each film coated tablet contains 500mg cefuroxime axetil U.S.P. in a pack of 10 tablets.

**Cefurex®** 125 suspension, each 5ml (after reconstitution) contains 125mg cefuroxime axetil U.S.P. in 50ml bottle as a dry powder for reconstitution.

**Cefurex®** 250 suspension, each 5ml (after reconstitution) contains 250mg cefuroxime axetil U.S.P. in 50ml bottle as a dry powder for reconstitution.

Hospital packs are available.

**In-active ingredients for Cefurex® tablets are**: Microcrystalline Cellulose, croscarmellose Sodium, colloidal silicon dioxide, Sodium Lauryl Sulphate, sodium Starch Glycolate, magnesium Stearate Powder, Sepifilm 752 White.

**In-active ingredients for Cefurex® d/s powder are**: Metolose, Sodium lauryl sulfate, Sucrose, Xanthan Gum, Methylparaben sodium, Propylparaben sodium, Sodium saccharine, Citric acid, Colloidal silicon dioxide, Strawberry flavor, Banana flavor, Titanium dioxide.

## STORAGE CONDITIONS

**Cefurex® tablets:** Should be stored below 30° C.

**Cefurex® suspension:** Store below 30° C. After reconstitution, store in a refrigerator (2° C - 8° C) and discard unused portion after 10 days.

**This is a medicament**

-Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

-Follow strictly the doctor's prescription, method of use and the instructions of pharmacist who sold the medicament.

-The doctor and the pharmacist are experts in medicine, its benefits and risks.

-Do not by yourself interrupt the period of treatment prescribed for you.

-Do not repeat the prescription without consulting your doctor.

-Keep out of reach of children.

Manufactured by: Middle East Pharmaceutical Company – **MIDPHARMA** – Jordan

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