

## DESCRIPTION:

Cefuroxime Axetil is an orally active prodrug of Cefuroxime. After oral administration, Cefuroxime Axetil is absorbed from the gastrointestinal tract and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa and blood to release Cefuroxime into the blood stream. Conversion to Cefuroxime, the microbiologically active form, occurs rapidly. The inherent properties of Cefuroxime are unaltered after its administration as Cefuroxime Axetil. Cefuroxime exerts its bactericidal effect by binding to an enzyme or enzymes referred to as penicillin-binding proteins (PBPs) involved in bacterial cell wall synthesis.

## COMPOSITION:

**Axibid™ 250 mg tablet:** Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg.

**Axibid™ 500 mg tablet:** Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg.

## CLINICAL PHARMACOLOGY:

### 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.

### Pharmacokinetics properties:

After oral administration Cefuroxime Axetil is absorbed from the gastrointestinal tract and rapidly hydrolysed 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. Protein binding has been variously stated as 33-50% depending on the methodology used. Cefuroxime is not metabolised 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 a 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. Serum levels of Cefuroxime are reduced by haemodialysis.

## INDICATIONS AND USAGE:

**Axibid™** (Cefuroxime Axetil) is indicated in the treatment of:

- ◆ Upper respiratory tract infections: ear, nose and throat infections such as otitis media, sinusitis, tonsillitis and pharyngitis.
- ◆ Lower respiratory tract infections: acute bronchitis, acute exacerbations of chronic bronchitis and pneumonia.
- ◆ Skin and soft tissue infections: such as furunculosis, pyoderma, and impetigo.
- ◆ Genito-urinary tract infections: such as pyelonephritis, urethritis, and cystitis.
- ◆ Gonorrhoea: acute uncomplicated gonococcal urethritis and cervicitis.
- ◆ Early Lyme disease & subsequent prevention of late Lyme disease.

## DOSEAGE AND ADMINISTRATION:

**Adolescents and Adults (13 years and older):** Most infections will respond to 250 mg b.i.d. In mild to moderate lower respiratory tract infections e.g. bronchitis 250 mg b.i.d. should be given. For more severe lower respiratory tract infections, or if pneumonia is suspected then 500 mg b.i.d. should be given. For urinary tract infections a dose of 125 mg b.i.d. is usually adequate; in pyelonephritis the recommended dose is 250 mg b.i.d. A single dose of one gram is recommended for the

treatment of uncomplicated gonorrhoea. Lyme disease in adults and children over the age of 12 years: the recommended dose is 500 mg b.i.d. for 20 days.

**Children:** The usual dose is 125 mg b.i.d. or 10 mg/kg b.i.d. to a maximum of 250 mg daily. For otitis media, in children less than 2 years of age the usual dosage is 125 mg b.i.d. or 10 mg/kg b.i.d. to a maximum of 250 mg daily and in children over 2 years of age, 250 mg b.i.d. or 15 mg/kg b.i.d. to a maximum of 500 mg daily. There is no experience in children under three months of age.

The usual course of therapy is seven days.

Cefuroxime Axetil may be given orally without regard to meals. Absorption is enhanced when Cefuroxime is administered with food.

## CONTRAINDICATIONS:

Patients with known hypersensitivity to cephalosporin antibiotics or who have experienced a major allergy to penicillin (anaphylaxis, angioneurotic oedema, urticaria).

## PRECAUTIONS:

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

## OVERDOSAGE:

*Signs and symptoms:* Overdosage of Cefuroxime can cause cerebral irritation leading to convulsions.

*Management:* Serum levels of Cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

## USE IN PREGNANCY & LACTATION:

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 early months of pregnancy. Cefuroxime is excreted in breast milk and consequently caution should be exercised when Cefuroxime Axetil is administered to a nursing mother.

## DRUG INTERACTIONS:

In common with other antibiotics, Cefuroxime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. As a false negative result may occur in the ferricyanide test, 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 in the alkaline picrate assay for creatinine.

Concurrent administration of probenecid increases the area under the mean serum concentration time curve by 50%. Serum levels of Cefuroxime are reduced by dialysis.

## SIDE EFFECTS:

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

## STORAGE CONDITION:

Store in a cool & dry place, protect from light. Keep out of the reach of children.

## COMMERCIAL PACK:

**Axibid™ 250 mg tablet:** Each box contains 2 x 7 tablets in Alu-Alu blister strip.

**Axibid™ 500 mg tablet:** Each box contains 1 x 7 tablets in Alu-Alu blister strip.