Turbocef®

(Cefuroxime)

DESCRIPTION

Cefuroxime Axetil is a semi-synthetic, broad-spectrum cephalosporin antibiotic for oral administration. Its molecular formula is C20H22N4O10S, and it has a molecular weight of 510.48. Cefuroxime Axetil is in the amorphous form. 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. This binding results in inhibition of bacterial cell wall synthesis and subsequent cell death. Specifically, Cefuroxime shows high affinity for PBP 3, a primary target for Cefuroxime in gram-negative organisms such as E. coli.

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). Tablets for sinus infections known, suspected, or considered potentially to be caused by beta-lactamase-producing *Haemophilus influenzae* or *Moraxella catarrhalis*.

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 and 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.*

DOSAGE AND METHOD OF ADMINISTRAITON
Turbocef Tablets may be administered without regard to meals.

Turbocef tablets:

Population/Infection	Dosage	Duration (days)
Adolescents and Adults (13 years and older)		
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.	5-10
Uncomplicated skin and skin-structure infections	250 or 500 mg b.i.d.	10
Uncomplicated urinary tract infections	250 mg b.i.d.	7-10
Uncomplicated gonorrhea	1,000 mg once	single dose
Early Lyme disease	500 mg b.i.d.	20
Pediatric Patients (who can swallow tablets whole)		
Acute otitis media	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10

Turbocef powder for oral suspension may be administered to pediatric patients ranging in age Pediatric Patients from 3 months to 12 years:

(Must be administered with food. Shake well each time before using.)			
Infection	Dosage	Daily Maximum Dose	Duration (days)
Pharyngitis/tonsillitis	20 mg/kg/day divided bid	500 mg	10
Acute otitis media	30 mg/kg/day divided bid	1000 mg	10
Acute bacterial maxillary sinusitis	30 mg/kg/day divided bid	1000 mg	10
Inpetigo	30 mg/kg/day divided bid	1000 mg	10

CONTRAINDICATIONS
Cefuroxime Axetil products are contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

ADVERSE REACTIONS
Hypersensitivity reactions: Anaphylaxis, angioedema, pruritus, rash, serum sickness-like reaction, and urticaria. *Gastrointestinal:* Pseudomembranous colitis *Hematologic:* Hemolytic anemia, leucopenia, pancytopenia, and thrombocytopenia and increased prothrombin time. *Hepatic:* Hepatic impairment including hepatitis and cholestasis, jaundice. *Neuroligic:* Seizure. *Skin:* Erythemia multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. *Urologic:* Renal dysfunction. *Others:* Diarrhea/loose stools, Nausea/vomiting, abdominal pain, abdominal cramps, Flatulence, indigestion, Headache, Vaginitis.

WARNING

Before therapy with Cefuroxime Axetil, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to Cefuroxime Axetil products or patients with a history of penicillin allergy. Caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented.

PRECAUTIONS

Cephalosporins, including Cefuroxime Axetil, should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function.

Cefuroxime Axetil, as with other broad-spectrum antibiotics, should be prescribed with caution in individuals with a history of colitis.

Risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy.

HIGH RISK GROUP

Pregnancy Category B: Cefuroxime Axetil has not been studied for use during labor and delivery. *Nursing Mothers:* Because Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime Axetil. *Pediatric Use:* The safety and effectiveness of Cefuroxime Axetil have been established for pediatric patients aged 3 months to 12 years for acute bacterial maxillary sinusitis based upon its approval in adults.

DRUG INTERACTION

Concomitant administration of probenecid with Cefuroxime Axetil increases the area under the serum concentration versus time curve by 50%. Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime Axetil compared with that of fasting state and tend to cancel the effect of postprandial absorption.

PHARMACEUTICAL PRECAUTIONS

Store in cool dry place & away from children.

PACKAGING

Turbocef® 250: Box contains 8/12/16 tablets. Each film coated tablet contains the equivalent of 250mg of cefuroxime as cefuroxime axetil USP.

Turbocef® 500: Box contains 4/8/12 tablets. Each film coated tablet contains the equivalent of 250mg of cefuroxime as cefuroxime axetil USP.

Turbocef® Powder for suspension: Each Amber glass bottle contains 50/60/70/100 ml suspension. After reconstitution each 5 ml contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg.

BEXIMCO PHARMA

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