Secomax

Cefuroxime Tablet / Powder for Suspension

Presentation

Secomax 250: Each film coated tablet contains Cefuroxime 250 mg (as Cefuroxime Axetil BP).
Secomax 500: Each film coated tablet contains Cefuroxime 500 mg (as Cefuroxime Axetil BP).
Secomax Powder for Suspension 70 ml: Each 5ml reconstituted suspension contains Cefuroxime 125 mg (as Cefuroxime Axetil BP).

Pharmacodynamic Properties

Cefuroxime is one of the bactericidal second-generation cephalosporins, which inhibits bacterial cell wall synthesis like other b-lactam antibiotics & is active against a wide range of Gram-positive and Gram-negative susceptible organisms including many b-lactamase producing strains. It has noteworthy activity against b-lactamase producing strains of *H. influenzae* & *N. gonorrhoea*. Cefuroxime kills bacteria by interfering the synthesis of bacterial cell wall, interferes with the transpeptidation process. It also binds with the penicillin binding protein & interferes with peptidoglycan synthesis.

Pharmacokinetic Properties

Cefuroxime Axetil is better absorbed if taken after food (approximately 60 %) & the absorption is not decreased by drugs which affect gastrointestinal motility eg. loperamide, diphenoxylate or castor oil. Absorption is decreased by concurrent administration of drugs such as ranitidine. Cefuroxime Axetil is completely hydrolyzed in the intestine to Cefuroxime. It takes 2-3 hours to reach peak plasma concentration after an oral dose. The plasma half-life is approximately 75 min & it is about 33% bound to serum protein. Cefuroxime is primarily eliminated by kidneys. Approximately 49% of an administered dose, after food, is recovered in the urine in 24 hours.

Indications

Secomax is indicated for the treatment of the following mild to moderately severe infections:

- ❖ Acute bacterial otitis media
- ❖ Acute bacterial maxillary sinusitis
- ❖ Lower respiratory tract infections including pneumonia, pharyngitis /tonsillitis
- ❖ Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis
- ❖ Skin-and Skin-Structure Infections including furunculosis, pyoderma and impetigo
- ❖ Urinary tract infections
- ❖ Bone and Joint Infections
- ❖ Uncomplicated and disseminated gonococcal Infections (Gonorrhea)
- ❖ Cervicitis
- ❖ Early Lyme disease (erythema migrans)
- ❖ Septicemia
- ❖ Meningitis
- ❖ Prophylaxis against infections in abdominal, pelvic, orthopedic, cardiac, pulmonary, esophageal and vascular surgery where there is increased risk for infection

Dosage and Administration

Type of infections	Dosage	Duration
Adolescents & adults (13 years & ebove)		
Pharyngitis or Tonsillitis	250 mg twice daily	10 days
Acute bacterial maxillary sinusitis	250 mg twice daily	10 days
Acute bacterial exacerbations of chronic bronchitis	250-500 mg twice daily	10 days
Secondary bacterial infections of acute bronchitis	250-500 mg twice daily	5-10 days
Uncomplicated skin & skin-structure infections	250-500 mg twice daily	10 days
Uncomplicated urinary tract infections	250 mg twice daily	7-10 days
Uncomplicated gonorrhea	1000 mg once	Single dose
	500 mg twice daily	
Pediatric patients (up to12 years who can swallow tablets whole)		
Acute otitis media	250 mg twice daily	10 days
Acute bacterial maxillary Sinusitis		
Suspension for Pediatric patients 3 months to 12 years (Shake the bottle well before each use)		
Pharyngitis or Tonsillitis	20 mg/kg/day in two divided doses	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
Impetigo		10 days

Contraindications

Patients with known hypersensitivity to cephalosporin group of drugs.

Side Effects

Generally Cefuroxime is well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.
Gastro-intestinal disturbances: loss of appetite, diarrhea (if severe diarrhea occurs Cefuroxime should be discontinued), changes in the color of stool, nausea, abdominal discomfort or pain, dyspepsia, vomiting, flatulence.
Central nervous system disturbances: Headache, dizziness.
Hepatological disturbance: Transient elevations of Aspartate transaminase (AST), Alanine transaminase (ALT) and Lactate dehydrogenase (LDH).
Hypersensitivity reactions: Rash, pruritus, urticaria.
Others: Hypersensitivity reactions, which usually subsided upon discontinuation of therapy; infrequent and reversible haematological changes; elevation of serum amylase, vaginal itching or discharge.

Precautions

Cefuroxime axetil, should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis.

Drug Interactions

Concomitant administration of probenecid with cefuroxime axetil tablets increases the AUC by 50%. Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime compared with that of fasting state and tend to cancel the effect of postprandial absorption. In common with other antibiotics, cefuroxime axetil may affect the gut flora, leading to lower estrogen re-absorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy Category: B. While all antibiotics should be avoided in the first trimester if possible. So it should be administered during pregnancy only if such use is considered essential. However, Cefuroxime has been safely used in later pregnancy to treat urinary and other infections.
Use in Lactation: Cefuroxime is excreted in human milk in small quantities, and consequently caution should be exercised when cefuroxime axetil is administered to a nursing mother.

Storage Condition

Secomax tablet & powder for suspension should be kept in a cool (15° - 30° C) and dry place and protected from direct sunlight. After reconstitution, the suspension should be used within 10 days.

Directions for Reconstitution of Suspension

Shake the bottle well before mixing water to loosen the powder. Add 40 ml (with the help of the provided cup) boiled and cooled water in the bottle and shake well to make 70ml suspension.

Informations for the patient

- ❖ Shake well before using the suspension
- ❖ Do not discontinue the therapy suddenly, without consulting your doctor
- ❖ Discard unused portion of reconstituted suspension after 10 days
- ❖ Keep away from the reach of children

Commercial Pack

Secomax 250: Each box contains 3 Alu-Alu blister packs of 4 tablets
Secomax 500: Each box contains 2 Alu-Alu blister packs of 4 tablets
Secomax Powder for Suspension 70 ml: Each bottle contains dry Powder for the preparation of 70 ml suspension.

Manufactured By :
GENERAL Pharmaceuticals Ltd.
Gazipur, Bangladesh
GENERAL Pharmaceuticals Ltd. ISO 9001:2000 Certified Company