CEFADROX

Tablets & Suspension

Composition

Cefadrox 125 Suspension
Each teaspoonful (5 ml) contains Cefadroxil (as monohydrate) 125 mg.

Cefadrox 250 Suspension
Each teaspoonful (5 ml) contains Cefadroxil (as monohydrate) 250 mg

Cefadrox Tablets
Each tablet contains Cefadroxil (as monohydrate) 500 mg.

Action

Cefadrox is a semi synthetic cephalosporin antibiotic intended for oral administration.

Cefadrox is rapidly absorbed after oral administration. Following single doses of 500 and 1000 mg, average peak serum concentrations were approximately 16 and 28 mg/ml, respectively. Measurable levels were present 12 hours after administration. Over 90% of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800 mg/ml during the period following a single 500-mg oral dose. Increases in dosage generally produce a proportionate increase in Cefadroxil urinary concentration. The urine antibiotic concentration, following a 1-gram dose, was maintained well above the MIC of susceptible urinary pathogens for 20 to 22 hours.

Cefadroxil is active against the following organisms in vitro:

- Beta-haemolytic streptococci
- Staphylococci including coagulase-positive, coagulase negative and penicillinase-producing strains:
  - *Streptococcus (Diplococcus) pneumoniae*
  - *Escherichia coil*
  - *Proteus mirabilis*
  - *Klebsiella species*
  - *Moraxella (Branhamelia) catarrhalis*

Susceptibility Tests
Quantitative methods that require measurement of zone diameters give the most precise estimates of antibiotic susceptibility. Standardized discs are available to test susceptibility by correlating the diameter of the zone of inhibition with MIC values for Cefadroxil. Organisms reported by the laboratory as being of intermediate susceptibility would suggest that they might be susceptible to Cefadroxil if high dosage is used, or if the infection is confined to tissues and fluids (e.g. urine) in, which high antibiotic levels are attained.
Resistant organisms are not likely to respond to therapy, and an alternative drug should be selected.

Indications

Cefadrox is indicated for the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

- Urinary tract infections caused by E. coli, P. mirabilis, and Klebsiella species.
- Skin and skin structure infections caused by staphylococci and/or streptococci.
- Pharyngitis and tonsillitis caused by group A beta-hemolytic streptococci. (Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefadrox is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of Cefadrox in the subsequent prevention of rheumatic fever are not available at present.)

"*Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated*."

Contraindications
Cefadroxil is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings
In penicillin-allergic patients, cephalosporin antibiotics should be used with great caution. There is clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins, and there are instances of patients who have had reactions to both drugs (including fatal anaphylaxis after parenteral use).

Any patient who has demonstrated a history of some form of allergy, particularly to drugs, should receive antibiotics cautiously and then only when necessary. No exception should be made with regard to Cefadroxil.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad-spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad-spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by Clostridium difficile is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin in vitro.

Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should he managed with fluid, electrolyte, and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by C. difficile. Other causes of colitis should also be considered.

Precautions
Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If a hypersensitivity reaction occurs, the drug should be discontinued and the patient treated with the usual agents (eg. epinephrine, or other pressor amines, antihistamines, or corticosteroids).

Cefadroxil should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50 ml/ min/1.73 M2).

In patients, with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy.

Prolonged use of Cefadroxil may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If super infection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Cefadroxil should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Pregnancy

Category B
There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers
Caution should be exercised when Cefadroxil is administered to a nursing mother.

Adverse Reactions

Gastrointestinal
Symptoms of pseudomembranous colitis can appear during antibiotic treatment. Nausea and vomiting have been reported rarely. Diarrhea and dysuria have also occurred.

Hypersensitivity
Allergies (in the form of rash, urticaria, and angioedema) have been observed. These reactions usually subsided upon discontinuation of the drug.

Other reactions have included genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, and minor elevations in serum transaminase. Stevens-Johnson syndrome has been rarely reported.

Dosage and Administration

Cefadrox is acid stable and may be administered orally without regard to meals. Administration with food may be helpful in diminishing potential gastrointestinal complaints occasionally associated with oral cephalosporin therapy.

Adults
Urinary Tract Infections
For uncomplicated lower urinary tract infections (i.e., cystitis) the usual dosage is 1 or 2 grams per day in single (qd) or divided doses (bid).

For all other urinary tract infections, the usual dosage is 2 grams per day in divided doses (bid).

Skin and Skin Structure Infections
For skin and skin structure infections, the usual dosage is 1 gram per day in single (qd) or divided doses (bid).

Pharyngitis and Tonsillitis
Treatment of group A beta-hemolytic streptococcal pharyngitis and tonsillitis - 1 gram per day in single (qd) or divided doses (bid) for 10 days.

Children
Urinary tract infections and for skin and skin structure infections
The recommended daily dosage is 30 mg/kg/day in divided doses every 12 hours.

Pharyngitis and tonsillitis
The recommended daily dosage is 30 mg/kg/day in single (qd) or divided doses (bid). In the treatment of beta-hemolytic streptococcal infections, a therapeutic dosage of Cefadrox should be administered for at least 10 days.

Patients with renal impairment
The dosage of Cefadroxil monohydrate should be adjusted according to creatinine clearance rates to prevent drug accumulation.

Patients with creatinine clearance rates over 50 ml/min may be treated as if they were patients having normal renal function.

Pharmaceutical Precautions

Reconstituted Cefadrox suspension may be kept for 7 days in a refrigerator, without significant loss of potency.

Presentation

Cefadrox 125 Suspension
Powder for the preparation of 60 ml.

Cefadrox 250 Suspension
Powder for the preparation of 60 ml.

Cefadrox Tablets
Box of 12 tablets.