DRUG DESCRIPTION

Cefuroxime is a semisynthetic, broad-spectrum cephalosporin antibiotic

<ptr>INDICATIONS

Pharyngitis/Tonsillitis
caused by Streptococcus pyogenes.

NOTE: The usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever, is penicillin given by the intramuscular route. Cefuroxime is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefuroxime in the subsequent prevention of rheumatic fever are not available. All isolates had to be sensitive to both penicillin and cefuroxime. There are no data from adequate and well-controlled trials to demonstrate the effectiveness of cefuroxime in the treatment of penicillin-resistant strains of 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).

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.

<PREGNANCY & LACTATION

Pregnancy Category B.
This drug should be used during pregnancy only if clearly needed.

Lactation
Because cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime.

Pediatric Use

The safety and effectiveness of Cefuroxime have been established for pediatric patients aged 3 months to 12 years for acute bacterial maxillary sinusitis based upon its approval in adults.

GERIATRIC USE

No overall differences in safety or effectiveness were observed between these subjects and younger adult subjects. The geriatric patients reported somewhat fewer gastrointestinal events and less frequent vaginal candidiasis compared with patients 12 to 64 years old; however, no clinically significant differences were reported between the elderly and younger adult patients.

DOSAGE AND ADMINISTRATION

Infection:

Adults and Children 12 yr of age and older
PO 125 to 500 mg twice daily
IV / IM 750 mg to 1.5g every 8 h.

Children younger than 12 yr of age
PO 125 to 250 mg twice daily.

Infants and Children older than 3 months of age
IV / IM 50 to 150 mg/kg/day (not to exceed adult dose) in equally divided doses every 6 to 8 h.

Bacterial Meningitis

Adults and Children 12 yr of age and older
IV / IM Up to 3 g every 8 h.

Infants and Children 3 mo to 12 yr of age
IV / IM 200 to 240?mg/kg/day in divided doses every 6 to 8 h.

Uncomplicated Gonorrhea

Adults and Children 12 yr of age and older
PO 1 g as single dose. IM 1.5 g as single dose.

Preoperative Prophylaxis
Adults
IV / IM 1.5 g 30 min to 1 h before surgery then 750 mg every 8 h for duration of surgery.

General advices
- Administer oral form with food to enhance absorption.
- Crushed tablets have strong, persistent bitter taste.
- When giving by IM route, shake IM suspension gently before administration. Aspirate to prevent injection into blood vessel. Inject deeply into large muscle (eg, upper outer quadrant of gluteus muscle or lateral thigh); massage well. Rotate injection sites.
- When giving by IV route, use direct intermittent infusion. Administer slowly over 3 to 5 min.
  Change IV sites every 48 to 72 h.
- For intermittent IV infusion with Y-type administration set, administer over 30 min. and temporarily stop other solutions at Y-site.
- For continuous infusion, reconstituted solution may be further diluted with D5W or sodium chloride 0.9%.

<ptr>IMPAIRED RENAL FUNCTION

Patients With Renal Failure: The safety and efficacy of Cefuroxime Axetil in patients with renal failure have not been established. Since cefuroxime is renally eliminated, its half-life will be prolonged in patients with renal failure.

When only serum creatinine is available, the following formula (Cockcroft's equation) may be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function:
Males: \[ \text{Weight (kg)} \times (140 - \text{age}) / 72 \times \text{serum creatinine} \]
Females: \[ 0.85 \times \text{male value} \]

Renal dose adjustment
- oral
  - When Creatinine clearance more than 10 ml/min
    no change needed in the dose.
  - When Creatinine clearance less than 10 ml/min

give 250mg q24h.

IV
When Creatinine clearance more than 20ml/min
750 mg to 1.5 gm IV q8h
When Creatinine clearance = 10-20 ml/min
750 mg q12h
When Creatinine clearance less than 10 ml/min
750 mg q24h

Hemodialysis:
IV:
750mg q24h. Repeat the dose at the end of dialysis.
PD: 750 mg q24h.

Oral:
Give 250 mg q24h. Repeat the dose after dialysis

<ptr>Over dose

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions.
Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis

<ptr>Contraindications

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

<ptr>Interactions with Laboratory or Diagnostic Testing

A false-positive reaction for glucose in the urine may occur with copper reduction tests (Benedict's or Fehling's solution or with CLINITEST tablets), but not with enzyme-based tests for glycosuria (e.g., CLINISTIX).
As a false-negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase method be used to determine blood / plasma glucose levels in patients receiving Cefuroxime.
The presence of cefuroxime does not interfere with the assay of serum and urine creatinine by the alkaline picrate method.

<ptr>DRUG INTERACTIONS
Aminoglycosides
Increased risk of nephrotoxicity with parenteral cefuroxime.

Probenecid
Inhibition of renal excretion of cefuroxime.

In common with other antibiotics, Cefuroxime Axetil may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

<ptr>Adverse Reactions

Hypersensitivity reactions have been reported: anaphylaxis, angioedema, pruritus, rash, serum sickness-like reaction, urticaria.

Gastrointestinal: Nausea; vomiting; diarrhea; anorexia; abdominal pain or cramps; flatulence; colitis, including pseudomembranous colitis.

Hematologic: Hemolytic anemia, leukopenia, pancytopenia, thrombocytopenia, and increased prothrombin time.

Hepatic: Hepatic impairment including hepatitis and cholestasis, jaundice.

Neurologic: Seizure.

Skin: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.

Urologic: Renal dysfunction

Hypersensitivity, including Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis; candidal overgrowth; serum sickness-like reactions (eg, skin rashes, polyarthritis, arthralgia, fever); phlebitis, thrombophlebitis, and pain at injection site.

For cephalosporin-class antibiotics:
Toxic nephropathy, aplastic anemia, hemorrhage, increased BUN, increased creatinine, false-positive test for urinary glucose, increased alkaline phosphatase, neutropenia, elevated bilirubin, and agranulocytosis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced.
If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

**Warnings/Precautions**

Before therapy with cefuroxime products is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefuroxime products, other cephalosporins, penicillins, or other drugs.

If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy.

If a clinically significant allergic reaction to cefuroxime products occurs, discontinue the drug and institute appropriate therapy. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefuroxime, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime may result in overgrowth of nonsusceptible microorganisms.

If superinfection occurs during therapy, appropriate measures should be taken.

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

Cephalosporins may be associated with a fall in prothrombin activity. Those at 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. Prothrombin time should be monitored in patients at risk and exogenous Vitamin K administered as indicated.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as 2 or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

References
FDA approved data
www.drugs.com
www.rxlist.com