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Cefuroxime Axetil (Ceftin)

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CEFTIN (cefuroxime axetil) TABLETS IN CLINICAL TRIALS

Multiple-Dose Dosing Regimens

7 to 10 Days Dosing

Using multiple doses of cefuroxime axetil tablets, 912 patients were treated with cefuroxime axetil (125 to 500 mg twice daily). There were no deaths or permanent disabilities thought related to drug toxicity. Twenty (2.2%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or almost certainly related to drug toxicity. Seventeen (85%) of the 20 patients who discontinued therapy did so because of gastrointestinal disturbances, including diarrhea, nausea, vomiting, and abdominal pain. The percentage of cefuroxime axetil tablet-treated patients who discontinued study drug because of adverse events was very similar at daily doses of 1,000, 500, and 250 mg (2.3%, 2.1%, and 2.2%, respectively). However, the incidence of gastrointestinal adverse events increased with the higher recommended doses.

The following adverse events were thought by the investigators to be possibly, probably, or almost certainly related to cefuroxime axetil tablets in multiple-dose clinical trials (n = 912 cefuroxime axetil-treated patients).

Table 4. Adverse Reactions-CEFTIN (cefuroxime axetil) Tablets
Multiple-Dose Dosing Regimens-Clinical Trials

Diarrhea/loose stools 3.7%	Incidence ? 1%
Nausea/vomiting 3.0%	
Transient elevation in AST 2.0%	
Transient elevation in ALT 1.6%	
Eosinophilia 1.1%	
Transient elevation in LDH 1.0%	
Abdominal pain	Incidence
Abdominal cramps	< 1% but > 0.1%
Flatulence	
Indigestion	
Headache	
Vaginitis	
Vulvar itch	
Rash	
Hives	
Itch	
Dysuria	
Chills	
Chest pain	
Shortness of breath	
Mouth ulcers	
Swollen tongue	
Sleepiness	
Thirst	
Anorexia	
Positive Coombs test	

section) CLINICAL STUDIES 5-Day Experience (see

In clinical trials using CEFTIN (cefuroxime axetil) in a dose of 250 mg twice daily in the treatment of secondary bacterial infections of acute bronchitis, 399 patients were treated for 5 days and 402 patients were treated for 10 days. No difference in the occurrence of adverse events was found between the 2 regimens.

In Clinical Trials for Early Lyme Disease With 20 Days Dosing

Two multicenter trials assessed cefuroxime axetil tablets 500 mg twice a day for 20 days. The most common drug-related adverse experiences were diarrhea (10.6% of patients), Jarisch-Herxheimer reaction (5.6%), and vaginitis (5.4%). Other adverse experiences occurred with frequencies comparable to those reported with 7 to 10 days dosing.

Single-Dose Regimen for Uncomplicated Gonorrhea

In clinical trials using a single dose of cefuroxime axetil tablets, 1,061 patients were treated with the recommended dosage of cefuroxime axetil (1,000 mg) for the treatment of uncomplicated gonorrhea. There were no deaths or permanent disabilities thought related to drug toxicity in these studies.

The following adverse events were thought by the investigators to be possibly, probably, or almost certainly related to cefuroxime axetil in 1,000-mg single-dose clinical trials of cefuroxime axetil tablets in the treatment of uncomplicated gonorrhea conducted in the United States.

Table 5. Adverse Reactions-CEFTIN (cefuroxime axetil) Tablets
1-g Single-Dose Regimen for Uncomplicated Gonorrhea-Clinical Trials

Nausea/vomiting 6.8%	Incidence ? 1%
Diarrhea 4.2%	
Abdominal pain	Incidence
Dyspepsia	< 1% but > 0.1%
Erythema	
Rash	
Pruritus	
Vaginal candidiasis	
Vaginal itch	
Vaginal discharge	
Headache	
Dizziness	
Somnolence	
Muscle cramps	
Muscle stiffness	
Muscle spasm of	
Tightness/pain in	
Bleeding/pain in	
Kidney pain	
Tachycardia	
Lockjaw-type	

Ceftin (cefuroxime axetil) For Oral Suspension In Clinical Trials

In clinical trials using multiple doses of cefuroxime axetil powder for oral suspension, pediatric patients (96.7% of whom were younger than 12 years of age) were treated with the recommended dosages of cefuroxime axetil (20 to 30 mg/kg/day divided twice a day up to a maximum dose of 500 or 1,000 mg/day, respectively). There were no deaths or permanent disabilities in any of the patients in these studies. Eleven US patients (1.2%) discontinued medication due to adverse events thought by the investigators to be possibly, probably, or almost certainly related to drug toxicity. The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or vomiting. During clinical trials, discontinuation of therapy due to the taste and/or problems with administering this drug occurred in 13 (1.4%) pediatric patients enrolled at centers in the United States.

The following adverse events were thought by the investigators to be possibly, probably, or almost certainly related to cefuroxime axetil for oral suspension in multiple-dose clinical trials (n = 931 cefuroxime axetil-treated US patients).

Table 6. Adverse Reactions-CEFTIN (cefuroxime axetil) for Oral Suspension
Multiple-Dose Dosing Regimens-Clinical Trials

Diarrhea/loose stools8.6%	Incidence ? 1%
Dislike of taste 5.0%	
Diaper rash 3.4%	
Nausea/vomiting 2.6%	
Abdominal pain	Incidence
Flatulence	< 1% but > 0.1%
Gastrointestinal	
Candidiasis	
Vaginal irritation	
Rash	

Hyperactivity	
Irritable behavior	
Eosinophilia	
Positive direct Coombs	
Elevated liver	
Viral illness	
Upper respiratory	
Sinusitis	
Cough	
Urinary tract	
Joint swelling	
Arthralgia	
Fever	
Ptyalism	

Postmarketing Experience With Ceftin (cefuroxime axetil) Products

In addition to adverse events reported during clinical trials, the following events have been identified during clinical practice in patients treated with CEFTIN (cefuroxime axetil) Tablets or with CEFTIN (cefuroxime axetil) for Oral Suspension and were reported spontaneously. Data are generally insufficient to allow an estimate of incidence or to establish causation.

General

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

Gastrointestinal

). **WARNINGS** Pseudomembranous colitis (see

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.

Cephalosporin-Class Adverse Reactions

In addition to the adverse reactions listed above that have been observed in patients treated with cefuroxime axetil, the following adverse reactions and altered -laboratory tests have been reported 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.

DOSAGE Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be **OVERDOSAGE** and **AND ADMINISTRATION** given if clinically indicated.