Ceftin (cefuroxime axetil) - Drug Summary

GlaxoSmithKline LLC

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Ceftin
(cefuroxime axetil)

THERAPEUTIC CLASS

Cephalosporin (2nd generation)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Pharyngitis/Tonsillitis

Mild to Moderate:
250mg tab q12h for 10 days

Acute Maxillary Sinusitis

Mild to Moderate:
250mg tab q12h for 10 days

Bronchitis

Mild to Moderate:
Acute Bacterial Exacerbations of Chronic Bronchitis: 250mg tab or 500mg tab q12h for 10 days

Secondary Bacterial Infections of Acute Bronchitis: 250mg tab or 500mg tab q12h for 5-10 days

Skin and Skin Structure Infections

Uncomplicated:
250mg tab or 500mg tab q12h for 10 days

Urinary Tract Infections

Uncomplicated:
250mg tab q12h for 7-10 days

Gonorrhea

Uncomplicated (Urethral, Endocervical, Rectal [in Females]):
1g tab as a single dose

Lyme Disease

Early Lyme Disease (Erythema Migrans):
500mg tab q12h for 20 days

PEDIATRIC DOSAGE & INDICATIONS

Skin and Skin Structure Infections

≥13 Years:
Uncomplicated: 250mg tab or 500mg tab q12h for 10 days

Urinary Tract Infections

≥13 Years:
Uncomplicated: 250mg tab q12h for 7-10 days

Gonorrhea

≥13 Years:
Uncomplicated (Urethral, Endocervical, Rectal [in Females]): 1g tab as a single dose

Lyme Disease

Early Lyme Disease (Erythema Migrans):
≥13 Years:
500mg tab q12h for 20 days

Pharyngitis/Tonsillitis

Mild to Moderate:
3 Months-12 Years: 20mg/kg/day sus divided bid for 10 days
Max: 500mg/day sus

≥13 Years: 250mg tab q12h for 10 days

Acute Otitis Media

3 Months-12 Years:
30mg/kg/day sus divided bid for 10 days
Max: 1g/day sus

Patients Who Can Swallow Tabs Whole: 250mg tab q12h for 10 days

Acute Maxillary Sinusitis

Mild to Moderate:
3 Months-12 Years: 30mg/kg/day sus divided bid for 10 days
Max: 1g/day sus

≥13 Years or Pediatric Patients <13 Years Who Can Swallow Tabs Whole: 250mg tab q12h for 10 days

Impetigo

3 Months-12 Years:
30mg/kg/day sus divided bid for 10 days
Max: 1g/day sus

Bronchitis

≥13 Years:
Mild to Moderate:
Acute Bacterial Exacerbations of Chronic Bronchitis: 250mg tab or 500mg tab q12h for 10 days

Secondary Bacterial Infections of Acute Bronchitis: 250mg tab or 500mg tab q12h for 5-10 days

DOSING CONSIDERATIONS

Renal Impairment
CrCl 10 to <30mL/min: Standard individual dose given q24h
CrCl <10mL/min (w/o Hemodialysis): Standard individual dose given q48h
Hemodialysis: Give a single additional standard dose at the end of each dialysis

ADMINISTRATION

Oral route

Tabs and sus are not bioequivalent and are not substitutable on a mg-per-mg basis
Pediatric patients ≥13 years who cannot swallow tabs whole should receive sus because the tab has a strong, persistent bitter taste when crushed

Sus
Take w/ food
Reconstitute 125mg/5mL w/ 37mL of water (for a volume of 100mL after reconstitution)
Reconstitute 250mg/5mL w/ 19mL of water (for a volume of 50mL after reconstitution) or 35mL of water (for a volume of 100mL after reconstitution)
Shake well before each use
Store reconstituted sus refrigerated between 2-8°C (36-46°F); discard reconstituted sus after 10 days

Tab
Take w/ or w/o food
Swallow whole w/o crushing

HOW SUPPLIED

Sus: 125mg/5mL [100mL], 250mg/5mL [50mL, 100mL]; Tab: 250mg, 500mg

WARNINGS/PRECAUTIONS

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions reported; d/c and institute appropriate therapy if an allergic reaction occurs. *Clostridium difficile*-associated diarrhea (CDAD) reported; may need to d/c if CDAD is suspected or confirmed. May result in bacterial resistance if used in the absence of proven or strongly suspected bacterial infection, or a prophylactic indication; consider possibility of superinfections w/ fungal or bacterial pathogens during therapy. Lab test interactions may occur. Caution in elderly. (Sus) Contains phenylalanine.

ADVERSE REACTIONS

Diarrhea, N/V, dislike of taste, diaper rash, Jarisch-Herxheimer reaction, vaginitis.

DRUG INTERACTIONS

May affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives. Drugs that reduce gastric acidity may result in a lower bioavailability; administer at least 1 hr before or 2 hrs after administration of short-acting antacids. Avoid H_2 antagonists and proton pump inhibitors. Probenecid increases plasma levels; coadministration is not recommended.

PREGNANCY AND LACTATION

Category B, caution in nursing.

MECHANISM OF ACTION

Cephalosporin (2nd generation); bactericidal agent that acts by inhibition of bacterial cell-wall synthesis.

PHARMACOKINETICS

Absorption: Absolute bioavailability (37% before food, 52% after food). **Distribution:** Plasma protein binding (50%); found in breast milk. **Metabolism:** Rapid hydrolysis via nonspecific esterases in the intestinal mucosa and blood. **Elimination:** Urine (50% unchanged).

Administration of variable doses resulted in different pharmacokinetic parameters.

ASSESSMENT

Assess for known hypersensitivity to therapy, other β-lactam antibacterial drugs (eg, penicillins, cephalosporins), or other allergens, renal impairment, pregnancy/nursing status, and possible drug interactions. For patients planning on using sus formulation, assess for phenylketonuria.

MONITORING

Monitor for anaphylactic reactions, CDAD, development of superinfection, and other adverse reactions.

PATIENT COUNSELING

Advise of potential benefits/risks of therapy. Inform that drug only treats bacterial, not viral, infections. Instruct to take exactly ud; inform that skipping doses or not completing full course of therapy may decrease effectiveness and increase the likelihood of bacterial resistance. Inform that diarrhea may occur and will usually end when therapy is discontinued. Instruct to contact physician as soon as possible if watery and bloody stools (w/ or w/o stomach cramps and fever) develop even as late as ≥2 months after having taken the last dose. Inform that therapy may cause allergic reactions in some individuals. Inform that sus contains phenylalanine (a component of aspartame). Counsel patients to consider alternate supplementary (non-hormonal) contraceptive measures during treatment.

STORAGE

Tab: 15-30°C (59-86°F). Dry Powder: 2-30°C (36-86°F). Reconstituted Sus: Immediately store refrigerated between 2-8°C (36-46°F); discard after 10 days.

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