

## Cephalexin

**Introduction:** Cephalexin is in a group of drugs called cephalosporin antibiotics and is used to fight bacteria in the body.

**Mechanism of action:** Inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs) which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

### Pharmacology:

**Absorption:** Delayed in young children

**Distribution:** Widely into most body tissues and fluids, including gallbladder, liver, kidneys, bone, sputum, bile, and pleural and synovial fluids; CSF penetration is poor; crosses placenta; enters breast milk

**Protein binding:** 6% to 15%

**Excretion:** Urine (80% to 100% as unchanged drug) within 8 hours

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

Respiratory tract infections caused by *Streptococcus pneumoniae* and *Streptococcus pyogenes*. Cephalexin is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cephalexin in the subsequent prevention of rheumatic fever are not available at present. Otitis media due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Moraxella catarrhalis*. Skin and skin structure infections caused by *Staphylococcus aureus* and/or *Streptococcus pyogenes*. Bone infections caused by *Staphylococcus aureus* and/or *Proteus mirabilis*. Genitourinary tract infections, including acute prostatitis, caused by *Escherichia coli*, *Proteus mirabilis*, and *Klebsiella pneumoniae*

### Dosage:

**Oral:** Children >1 year: Dosing range: 25-50 mg/kg/day every 6-8 hours; more severe infections: 50-100 mg/kg/day in divided doses every 6-8 hours; maximum: 4 g/24 hours

**Otitis media:** 75-100 mg/kg/day in 4 divided doses

**Streptococcal pharyngitis, skin and skin structure infections:** 25-50 mg/kg/day divided every 12 hours

**Uncomplicated cystitis:** Children >15 years: Refer to Adults dosing

Prophylaxis of bacterial endocarditis (dental, oral, respiratory tract, or esophageal procedures): 50 mg/kg 1 hour prior to procedure (maximum: 2 g)

**Dosing adjustment in renal impairment:** Adults:  $Cl_{cr} < 10$  mL/minute: 250-500 mg every 12 hours

**Hemodialysis:** Moderately dialyzable (20% to 50%)

**Side effects:**

**Gastrointestinal** — Onset of pseudomembranous colitis may occur during or after antibacterial treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. Dyspepsia, gastritis, and abdominal pain have also occurred. Transient hepatitis and cholestatic jaundice have been reported rarely.

**Hypersensitivity** — Allergic reactions in the form of rash, urticaria, angioedema, and, rarely, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. In some of these reactions, supportive therapy may be necessary. Anaphylaxis has also been reported. Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorder. Reversible interstitial nephritis has been reported rarely. Eosinophilia, neutropenia, thrombocytopenia, hemolytic anemia, and slight elevations in AST and ALT have been reported.

**Precautions:**

**General:** Prolonged use of Cephalexin may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection 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. Cephalexin should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended. 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.

**Pregnancy:** There are, however, no adequate and well-controlled studies in pregnant women.

**Nursing Mothers:** The excretion of cephalexin in human milk increased up to 4 hours after a 500-mg dose; the drug reached a maximum level of 4 µg/mL, then decreased gradually, and had disappeared 8 hours after administration. Caution should be exercised when Cephalexin is administered to a nursing woman.

**Pediatric Use:** Cephalexin should only be used in children and adolescents capable of ingesting the capsule.

**Geriatric Use:** Use with caution in geriatric patients. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

**Contraindications:** Hypersensitivity to cephalexin, any component of the formulation, or other cephalosporins

**How supplied:** Customized as per request.