

CEFALEX

Capsules & Suspension

Composition

Cefalex 250 Capsules

Each capsule contains Cephalexin (as monohydrate) 250 mg.

Cefalex 500 Capsules

Each capsule contains Cephalexin (as monohydrate) 500 mg.

Cefalex 125 mg suspension

Each 5 ml of the reconstituted suspension contains 125 mg Cephalexin (as monohydrate) .

Cefalex 250 mg suspension

Each 5 ml of the reconstituted suspension contains 250 mg Cephalexin (as monohydrate) .

Action

Cephalexin is a semisynthetic cephalosporin antibiotic drug. It is bactericidal, acting by inhibition of bacterial cell wall synthesis.

Cefalex is intended for oral administration. It is stable in gastric acid, and may be administered without regard to meals. Cefalex is rapidly and almost completely absorbed from the upper gastrointestinal tract. Its use is therefore associated with a relatively low incidence of gastrointestinal side effects.

Peak blood levels are reached within 1 hour of administration. They are comparable to those attained with equivalent doses of intramuscular cephaloridine, and exceed those obtained with equivalent doses of intramuscular cephalothin.

Cefalex is widely distributed in the tissues and high concentrations are achieved in all organs, especially the kidneys and liver. Cefalex is excreted unchanged in urine.

Cephalexin enjoys a wide margin of safety, and may be administered to the majority of penicillin-sensitive patients.

Cephalexin has been shown to be active in vitro against the following microorganisms:

- staphylococci (including penicillinase-producing strains)
- β -hemolytic streptococci
- *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*)
- *Corynebacterium diphtheria*
- *Escherichia coli*
- *Proteus mirabilis*
- *Klebsiella pneumoniae*
- *Neisseria gonorrhoea*
- *Neisseria meningitidis*
- *Salmonella species*
- *Shigella species*
- Some strains of *Haemophilus influenza*
- *Moraxella (Branhamella) catarrhalis*.

Most strains of enterococci (*Streptococcus faecalis*) and a few strains of staphylococci are resistant to Cephalexin.

Most strains of Enterobacter species, *Proteus vulgaris* and *Morganella morganii* (formerly *Proteus morganii*) are resistant. Methicillin-resistant staphylococci, *Pseudomonas* species and *Herellea* species are resistant to Cephalexin.

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 Cephalexin. Organisms reported by the laboratory as being of intermediate susceptibility would suggest that they might be susceptible to Cephalexin 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

Cefalex is indicated for the treatment of the following infections, when caused by susceptible organisms:

- Upper and lower respiratory tract infections
- Otitis media
- Genitourinary tract infections and acute prostatitis
- Skin and soft tissue infections
- Bone infections.

Contraindications

Known hypersensitivity to a cephalosporin-type antibiotic drug.

Warnings

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

Cephalosporin C derivatives should be administered with caution to penicillin-sensitive patients.

Serious acute hypersensitivity reactions may require adrenaline and other emergency measures.

There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins. Patients have been reported to have severe reactions (including anaphylaxis) to both types of drug.

Any patient who has demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously.

Pregnancy

Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Nursing Mothers

Cephalexin appears in breast milk. This should be taken into account when prescribing Cephalexin to a nursing mother.

Adverse Reactions

The most frequent side effect is diarrhea, but this is rarely severe enough to warrant cessation of therapy.

Symptoms of pseudomembranous colitis may appear, either during or after antibiotic treatment.

Nausea, vomiting, dyspepsia and abdominal pain have occasionally been reported.

Allergies such as rash, urticaria and angioedema, and rarely, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been observed, but these subside upon discontinuation of the drug.

Anaphylaxis has also been reported.

Other reactions include genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorders. Rare cases of reversible interstitial nephritis have been reported.

Eosinophilia, neutropenia, thrombocytopenia and slight elevations in SGOT and SGPT have been reported.

Precautions

If an allergic reaction to Cephalexin occurs, the drug should be discontinued and the patient treated with the usual agents (e.g. adrenaline or other pressor amines, antihistamines, or corticosteroids).

Cephalexin should be administered with caution in the presence of impaired renal function.

Prolonged use of Cephalexin may result in the overgrowth of nonsusceptible organisms. Repeated evaluation of the patient's condition is essential.

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

Pseudomembranous colitis has been reported with virtually all antibiotics, including cephalosporins. Therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use. Mild cases of pseudomembranous colitis may respond to drug discontinuation alone.

Moderate to severe cases should be managed with fluid and electrolyte and protein supplementation, as indicated.

Diagnostic Interference

A false-positive reaction for glucose in the urine may occur with Benedict's solution, Fehling's solution, or with Clinistest tablets. This has not been observed with enzyme-based tests such as Clinistix and Testape.

Positive direct Coombs' tests have been reported during treatment with cephalosporins. These may also occur in neonates whose mothers received cephalosporins before parturition.

Dosage and Administration

Susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

Adults

The daily dosage ranges from 1-4 gram, in divided doses. The usual dosage is 250 mg, every 6 hours.

A dosage of 500 mg, every 12 hours may be administered for the treatment of Streptococcal pharyngitis, skin and soft-tissue infections, and uncomplicated cystitis in patients over 15 years of age. Cystitis therapy should be continued for 7-14 days.

For more severe infections or those caused by less susceptible organisms, larger doses may be required. If a daily dosage greater than 4 gram is needed, the administration of a parenteral cephalosporin should be considered.

Children

25-50 mg/kg body weight, in 4 divided doses.

For streptococcal pharyngitis in patients over 1 year of age and for skin and soft-tissue infections, the total daily dosage may be divided into two 12-hourly doses.

In severe infections, the dosage may be doubled.

For otitis media, 75-100 mg/kg body weight/day, in 4 divided doses, is required.

In the treatment of β -hemolytic streptococcal infections, the patient should be treated with Cefalex for not less than 10 days.

Over Dosage

Manifestations

Symptoms of over dosage may include nausea, vomiting, epigastric distress, diarrhea and hematuria. If other symptoms are present, they are probably secondary to an underlying disease state, an allergic reaction, or toxicity due to ingestion of a second medication.

Treatment

Unless 5-10 times the normal dose of Cephalexin has been ingested, gastrointestinal decontamination should not be necessary.

Protect the patient's airway and support ventilation and perfusion. Continuously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal that, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal.

Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of Cephalexin.

Pharmaceutical Precautions

Reconstituted Cefalex suspension may be kept for 10 days in a refrigerator, without significant loss of potency.

Presentation

Cefalex 250 Capsules

Box of 16 capsules.

Cefalex 500 Capsules

Box of 16 capsules.

Cefalex 125 Suspension

Powder for the preparation of 60 ml, 100 ml suspension.

Cefalex 250 Suspension

Powder for the preparation of 60 ml, 100 ml suspension.