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1. Serious hypersensitivity (anaphylaxis)

1.2 Otitis Media

1.3 Skin and Skin Structure Infections

1.4 Bone Infections

1.5 Genitourinary Tract Infections

2.1 Adults and Pediatric Patients at Least 15 Years of Age

2.2 Pediatric Patients (over 1 year of Age)

2.3 Adults and Pediatric Patients at Least 15 Years of Age With Renal Impairment

3. DOSAGE FORMS AND STRENGTHS

4. CONTRAINDICATIONS

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6. DOSAGE AND ADMINISTRATION

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2.2 Pediatric Patients (over 1 year of Age)

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2.4 Seizure Potential

2.5 Direct Coombs’ Test Seroconversion

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3. DAXBIA™ CEPHALEXIN CAPSULES, USP

4. CONTRAINDICATIONS

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17. FOR PATIENTS COUNSELING
Cephalexin has the administration. It is In cases of uncomplicated urinary tract infection only, susceptibility of describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid Diffusion Techniques susceptibility of bacteria to antimicrobial compounds. The zone size provides an estimate of the susceptibility of event of an overdose, institute general supportive measures. A report of Susceptible (S) indicates that the antimicrobial drug is likely to inhibit growth of the pathogen if the bacteria to antimicrobial compounds. The zone size should be determined using a standardized test method. MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test methods (broth or agar). 8. USE IN SPECIFIC POPULATIONS 8.1 Pregnancy (Category B) There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Cephalexin has been shown to be active against the following bacteria in vitro: Enterobacter spp., Morganella morganii, Acinetobacter calcoaceticus, S. Penicillin-resistant, and 1.5 times the maximum the closest highest concentrations usually achievable at the infection site, other therapy should be selected. 13. NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility No information is available about the interaction of cephalexin and metformin following multiple doses Drug Interactions Absorption: Cephalexin is a bactericidal agent that acts by the inhibition of bacterial cell-wall synthesis. Antimicrobial Activity Methicillin-resistant staphylococci and most isolates of enterococci are resistant to cephalexin. Cephalexin is 17. Probenecid The renal excretion of cephalexin is inhibited by probenecid. Co-administration of probenecid with cephalexin is 8.1.3 Pregnancy (Category B) Pregnancy is not a contraindication for the use of cephalexin. The use of cephalexin during pregnancy should be limited to those cases where, in the opinion of the investigator, the benefits outweigh the potential risks. However, the effects of cephalexin on reproductive performance of either drug. 8.4 Pediatric Use 8.4.1 Children The safety and effectiveness of cephalexin in pediatric patients was established in clinical trials for the doses described in the dosage and administration section (see Dosage and Administration (2.3)). Cephalexin has been shown to be active against the following: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae, and Moraxella catarrhalis. 12.1 Mechanism of Action Cephalexin is a semisynthetic penicillin antibacterial drug intended for oral administration. It is a penicillin of the semisynthetic penicillins and is structurally related to penicillin G. Cephalexin has the following structural formula: Each capsule contains cephalexin monohydrate equivalent to 333 mg of cephalexin. The 333 mg capsules contain anhydro lactose, colloidal silicon dioxide, magnesium stearate, FD & C Blue No. 1, D & C Yellow No. 10, gelatin, sodium lauryl sulphate, titanium dioxide and FD & C Yellow No. 6. The imprinting ink contains; shellac, propylene glycol, starch, ammonium sulphate and black iron oxide. 12.6 Microbiology Mechanism of Action Cephalexin is a semisynthetic penicillin antibacterial drug [see Microbiology (12.4)]. 12.3 Pharmacokinetics Absorption: Cephalexin is acid stable and may be given without regard to meals. Following doses of 250 mg, 500 mg, and 1000 mg, average peak serum levels of approximately 9, 18, and 32 mcg/ml, respectively, were obtained at 1 hour. Serum levels were detectable 6 hours after administration (at a level of detection of 0.2 mcg/ml). Distribution: Cephalexin is approximately 10% to 15% bound to plasma proteins. Excretion: Cephalexin is excreted in the urine by glomerular filtration and tubular excretion. Studies showed that over 90% of the drug was excreted unchanged in the urine within 8 hours. During this period, peak urine concentrations of about 40 mcg/ml were attained. This drug is not dialyzable. 13.7 Long-term Safe storage is required when the drug is discontinued. Sometimes, frequent watery or bloody diarrhea may occur and may be a sign of more serious intestinal infection. If severe watery or bloody diarrhea develops, advise patients to seek medical advice from their healthcare provider. 13.4 Pathological Effects Cephalexin is approximately 10% to 15% bound to plasma proteins. Excretion: Cephalexin is excreted in the urine by glomerular filtration and tubular excretion. 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