Antibacterial

CCC5y1 MYS-004
R.O.C. Reg. No.:029172

CEPHANMYCIN CAPSULE 500MG

Ingredient(s): Each capsule contains:

Cephalexin 500mg

Pharmacology :

Pharmacodynamic:

Cephanmycin is a first-generation cephalosporin antibiotic. Its bactericidal action depends on the ability to reach and bind penicillin-binding proteins located in bacterial cytoplasmic membranes. Cephalexin inhibits bacterial septum and cell wall synthesis, probably by acylation of membrane-bound transpeptidase enzymes. This prevents cross-linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity. Also, cell division and growth are inhibited, and elongation of susceptible bacteria and lysis frequently occur. Rapidly dividing bacteria are those most susceptible to the action of cephalosporins.

Cephalexin has been shown to be active against many gram-positive aerobes including penicillinase-producing *Staphylococcus aureus*, penicillin-susceptible strains of *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*. Other susceptible gram-negative strains include *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Moraxella (Branhamella) catarrhalis*, and *Proteus mirabilis*.

Methicillin-resistant staphylococci and most strains of enterococci *(Enterococcus faecalis* [formerly *Streptococcus faecalis*]) are reisistant to cephalosporins, including Cephalexin. It is not active against most strains of *Enterobacter* spp., *Morganella morganii*, and *Proteus vulgaris*. It has no activity against *Pseudomonas* spp., or *Acinetobacter calcoaceticus*.

Pharmacokinetics:

Cephalexin is acid stable and may be given without regard to meals. It is rapidly absorbed after oral administration. Following doses of 250mg, 500mg, and 1g, average peak serum levels of approximately 9, 18, and 32µg/mL respectively were obtained at 1 hour. Measureable levels were present 6 hours after administration. Cephalexin is excreted in the urine by glomerular filtration and tubular secretion. Studies showed that over 90% of the drug was excreted unchanged in the urine within 8 hours. During this period, peak urine concentrations following the 250mg, 500mg, and 1g doses were approximately 1000, 2200, and 5000µg/mL respectively.

Indication(s):

Treatment of the following infections caused by susceptible strains of microorganisms:

1. Respiratory tract infections caused by *S. pneumoniae* and *S. pyogenes*.
2. Otitis media due to *S. pneumoniae, H. influenzae*, staphylococci, streptococci, and *M. catarrhalis*.
3. Skin and skin structure infections caused by staphylococci and/or streptococci.
4. Bone infections caused by staphylococci and/or *P. mirabilis*.
5. Genitourinary tract infections, including acute prostatitis, caused by *E. coli, P. mirabilis*, and *K. pneumoniae*.

Route of Administration:

To be taken orally.

Dosage and Administration :

Adults: The usual dosage is 250mg every 6 hours.

Streptococcal pharyngitis, skin and skin structure infections, and uncomplicated cystitis: 500mg every 12 hours. Cystitis therapy should be administered only to patients over 15 years of age and should continue for 7 to 14 days.

For more severe infections or those caused by less susceptible organism, larger doses up to 4g daily may be needed.

Contraindication(s):

Contraindicated in patients with known allergy to cephalosporin group of antibiotics.

Side Effect(s) / Adverse Reaction(s):

Gastrointestinal-Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect reported is diarrhea but it was very rarely severe enough to warrant cessation of therapy. 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 subside upon discontinuation of the drug. In some of these reactions, supportive therapy may be necessary. 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 disorder. Reversible nephritis has been reported rarely. Eosinophilia, neutropenia, thrombocytopenia, and slight elevations in AST and ALT have been reported.

Precaution(s) / Warning(s):

1. Cephanmycin should be given cautiously to penicillin-sensitive patients because of partial cross-allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both drugs.
2. Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Therefore, it is important to consider the diagnosis of pseudomembranous colitis in patients with diarrhea subsequent to the administration of antibiotics.
3. Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
4. Cephanmycin should be administered with caution in the presence of markedly impaired renal function especially elderly patients. The dosage may be lowered if necessary.
5. Prolonged use of Cephanmycin may result in the overgrowth of non-susceptible organisms. Appropriate measures should be taken if superinfection occurs during therapy.

Interaction with Other Medicaments:

1. Adverse effects could potentially arise from co-administration of Cephalexin and metformin by inhibition of tubular secretion. In healthy subjects given single 500mg doses of Cephalexin and metformin, plasma metformin mean C_{max} and AUC increase by an average of 34% and 24%, respectively, and metformin mean renal clearance decreased by 14%. No information is available about the interaction of metformin and Cephalexin following multiple doses of either drug.
2. Concomitant administration of oral probenecid competitively inhibits tubular secretion resulting in higher and more prolonged serum concentration of Cephalexin.

Pregnancy and Lactation:

Cephalosporins cross the placenta. Adequate and well-controlled studies in humans have not been established. However, studies in animals have not shown that Cephalexin cause adverse effects in the fetus.

Cephalexin showed no enhanced toxicity in weanling and newborn rats as compared with adult animals. Nevertheless, because the studies in humans cannot rule out the possibility of harm, Cephanmycin should be used during pregnancy only if clearly needed.

Cephalexin is excreted in breast milk but in low concentration (maximum level reached 4µg/mL). Caution should be exercised when Cephanmcyin is administered to a nursing woman.

Symptoms and Treatment for Overdosage, and Antidote(s):

Signs and Symptoms

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

Treatment

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

Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, 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.

Shelf-Life:

Plastic bottle: 3 years from the date of manufacture.
Blister packing: 2 years from the date of manufacture.

Storage Condition(s):

Store at temperature below 30ºC. Protect from light and moisture. Keep medicine out of reach of children.

Product Description & Packing(s):

A green cap and pale green body hard gelatin capsule, both cap and body imprinted with " CCC 500 " in black letters, with containing white to off white powder. ·

Plastic bottle of 1000's for export only.
Blister packing of 10'sx10, 10'sx100.

Manufacturer:
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