Axcel®

CEPHALEXIN

CAPSULES

AXCEL CEPHALEXIN-250 CAPSULES

COMPOSITION:

Each capsule contains
Cephalexin Monohydrate
equivalent to Cephalexin 250mg

PRESENTATION:

Pink / ruby red hard gelatin capsule, size 2.

AXCEL CEPHALEXIN-500 CAPSULES

COMPOSITION:

Each capsule contains
Cephalexin Monohydrate
equivalent to Cephalexin 500mg

PRESENTATION:

Pink / purple hard gelatin capsule, size 0.

INDICATIONS:

Axcel Cephalexin Capsule is indicated in the treatment of the following infections:
-Respiratory tract infection
-Otitis media
-Skin and soft tissue infections
-Bone and joint infections
-Genito-urinary tract infections, including acute prostatitis
-Dental infections

PHARMACOLOGY:

Mechanism of Action:

Pharmacotherapeutic gtoup: Antibacterials for systemic use; Other beta-lactam antibacterials, ATC code: J01DB01
In vitro tests demonstrate that cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. Cephalexin is active against the following organisms *in vitro*: Beta-haemolytic streptococci, Staphylococci (including coagulase-positive, coagulase-negative and penicillinase-producing strains), *Streptococcus pneumoniae, Escherichia coli,* Klebsiella species, *Proteus mirabilis, Haemophilus influenzae, Branhamella catarrhalis.* Most strains of enterococci (*Streptococcus faecalis*) and a few strains of Staphylococci are resistant to cephalexin. It is not active against most strains of Enterobacter species, *Morganella morganii* and *Pr. vulgaris.* It has no activity against Pseudomonas or Herellea species or *Acinetobacter calcoaceticus.* Penicillin-resistant *Streptococcus pneumonia* is usually cross-resistant to beta-lactam antibiotics. When tested by *in-vitro* methods, Staphylococci exhibit cross-resistance between cephalexin and methicillin-type antibiotics.

Pharmacokinetics:

Cephalexin is acid stable and maybe given without regard to meals. Cephalexin is almost completely absorbed from the gastrointestinal tract, and 75 - 100% is rapidly excreted in active form in the urine. Absorption is slightly reduced if the drug is administered with food. The half-life is approximately 60 minutes in patients with normal renal function. Haemodialysis and peritoneal dialysis will remove Cephalexin from the bllod. Peak blood levels are achieved one hour after administration, and therapeutic levels are maintained for 6 - 8 hours. Approximately 80% of the active drug is excreted in the urine within 6 hours. No accumulation is seen with dosages above therapeutic maximum 4g/day. The half-life maybe increased in neonates due to their renal immaturity, but there is no accumulation when given at up to 50mg/kg/day.

DOSAGE AND ADMINISTRATION:

For oral administration only.

Adult:

The adult dosage ranges from 1 - 4g daily in divided doses; most infections will respond to a dosage of 500mg every 8 hours. For skin and soft tissue infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the usual dosage is 250mg every 6 hours, or 500mg every 12 hours.

For more severe infections or those caused by less susceptible organisms, larger doses maybe needed.
If daily doses of Cephalexin greater than 4g are required, parenteral cephalosporins, in appropriate doses, should be considered.

The elderly and patients with impaired renal function:

As for adults. Reduce dosage if renal function is markedly impaired (refer Precaution section).

Children:

The usual recommended daily dosage for children is 25 - 50mg/kg/day in divided doses.

For skin and soft tissues infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the total daily dose maybe divided and administered every 12 hours. For most infections the following schedule is suggested:
5 to 12 years : 250mg 3 times daily.

In severe infections, the dosage maybe doubled. The maximum daily dose is 4g daily. In the therapy of otitis media, clinical studies have shown that a dosage of 75 to 100mg/kg/day in 4 divided doses is required.

In the treatment of beta-haemolytic streptococcal infections, a therapeutic dose should be administered for at least 10 days.

CONTRAINDICATION:

Contraindicated in patient with known allergy to the cephalosporin group of antibiotics.

PRECAUTION:

Before instituting therapy with Cephalexin, every effort should be made to determine whether the patient has had previous hypersensitivity reactions to the cephalosporins, penicillins, or other drugs. Cephalexin should be given cautiously to penicillin-sensitive patients. There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and cephalosporins. Patients have had severe reactions (including anaohylaxis) to both drugs.
Pseudomembranous colitis has been reported with virtually all broad-spectrul antibiotics, including macrolides, semi-synthetic penicillins, and cephalosporins. It is important, therefore, to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening. Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken.
If an allergic reaction to Cephalexin occurs, the drug should be discontinued and the patient treated with the appropriate agents.
Prolonged use of Cephalexin may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.
Cephalexin should be administered with caution in the presence of markedly impaired renal function. Careful clinical and laboratory studies should be made because safe dosage may be lower than that usually recommended.
Positive direct Coombs' tests have been reported during treatment with the Cephalosporin antibiotics.
In haematological studies, or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side, or in Coombs' testing of newborns whose have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.
A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions, or with copper sulphate test tablets.
Acute generalized exanthematous pustulosis (AGEP) has been reported in association with Cephalexin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, Cephalexin should be withdrawn immediately and an alternative treatment considered. Most of these reactions occurred most likely in the first week during treatment.

Use in Pregnancy:

Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing Axcel Cephalexin Capsule in pregnancy women.

Use in Lactation:

The excretion of Cephalexin in human breast milk increased up to 4 hours following a 500mg dose. The drug reached a maximum level of 4 mg/ml, then decreased gradually and had disappeared 8 hours after administration. Caution should be exercised when Cephalexin is administered to a nursing woman.

SIDE EFFECTS:

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 has been diarrhoea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Hypersensitivity: Allergic reactions have been observed in the form of rash, urticaria, angioedema, and rarely erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. These reactions usually subsided upon discontinuation of the drug, although in some cases supportive therapy may be necessary. Anaphylaxis has also been reported.

Haemic and lymphatic system: Eosinophilia, neutropenia, thrombocytopenia and haemolytic anaemia have been reported.

Skin and subcutaneous tissue disorders (frequency: not known): Acute generalized exanthematous pustulosis (AGEP).

Other: These have included genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, and joint disorder. Reversible interstitial nephritis has been reported rarely. Slight elevations in AST and ALT have been reported.

DRUG INTERACTIONS:

As with other beta-lactam drugs, renal excretion of Cephalexin is inhibited by probenecid.
In a single study of 12 healthy subjects given single 500mg doses of Cephalexin and Metformin, plasma Metformin Cmax and AUC increased by an average of 34% and 24%, respectively, and Metformin renal clearance decreased by an average of 14%. No side effects were reported in the 12 healthy subjects in this study. No information is available about the interaction of Cephalexin and Metformin following multiple dose administration. The clinical significance of this study is unclear, particularly as no cases of "lactic acidosis" have been reported in association with concomitant Metformin and Cephalexin treatment.
Hypokalaemia has been described in patients taking cytotoxic drugs for leukaemia when they are given Gentamicin and Cephalexin.

OVERDOSAGE AND TREATMENT:

Symptoms of oral overdosage may include nausea, vomiting, diarrhoea, epigastric distress, and haematuria. In the event of severe overdosage, general supportive care is recommended, including close clinical and laboratory monitoring of haematological, renal and hepatic functions, and coagulation status until the patient is stable. Forced diuresis, peritoneal dialysis, haemodialysis, or charcoal haemoperfusion have not been established as beneficial for an overdose of Cephalexin. It would be extremely unlikely that one of these procedures would be indicated.

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

Paediatric Population:
There have been reports of haematuria, without impairment of renal function, in children accidentally ingesting more than 3.5 g of Cephalexin in a day. Treatment has been supportive (fluids) and no sequelae have been reported.

STORAGE:
Store below 30^{o}C. Protect from light.

LIST OF EXCIPIENTS:
Capsule Contents:
Lactose, Purified Talc, Sodium Lauryl Sulphate and Magnesium Stearate.

Capsule Shell for Axcel Cephalexin-500 Capsule:
Gelatin, Titanium Dioxide, Azorubine, FD&C Blue 1, D&C Red 28 and FD&C Yellow 6.

Capsule Shell for Axcel Cephalexin-250 Capsule:
Gelatin, Titanium Dioxide, Azorubine, FD&C Blue 1, D&C Red 28, FD&C Yellow 6 and Quinoline Yellow.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:
Axcel Cephalexin - 250 Capsule: Available in blister pack of 10 x 10's.

Axcel Cephalexin - 500 Capsule: Available in blister pack of 10 x 10's.

Further information can be obtained from pharmacist, physician or the manufacturer.

AXCEL CEPHALEXIN-250 CAPSULES : MAL20014216AZ
AXCEL CEPHALEXIN-500 CAPSULES : MAL20014217AZ

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