



AXCEL[®]
CEPHALEXIN-250
SUSPENSION

COMPOSITION:

Each 5ml contains
Cephalexin Monohydrate
equivalent to Cephalexin 250mg

PRESENTATION:

White colour powder which gives a pink coloured suspension with strawberry flavour when reconstituted.

INDICATIONS:

Treatment of infections caused by susceptible bacteria. Respiratory tract infections: acute and chronic bronchitis and infected bronchiectasis. Ear, nose and throat infections; otitis media, mastoiditis, sinusitis, follicular tonsillitis and pharyngitis. Urinary tract infections; acute and chronic pyelonephritis, cystitis and prostatitis. Prophylaxis of recurrent urinary tract infection. Gynaecological and obstetric infections. Skin, soft-tissue and bone infections. Gonorrhoea (when Penicillin is not suitable). Dental procedures: treatment of dental infections. As prophylaxis treatment for patients with heart disease undergoing dental treatment as an alternative to penicillin.

PHARMACOLOGY:

Mechanism of Action:

Cephalexin is an oral broad-spectrum antibiotic belonging to the group known as cephalosporins. In adequate concentrations it is bactericidal for sensitive proliferating microorganisms by inhibiting the biosynthesis of the cell wall. It is active against the following pathogens:

Gram Positive

Staphylococci (coagulase positive as well as penicillinase-producing strains), Streptococci, pneumococci, *Corynebacterium diphtheriae*, *Bacillus anthracis*, Clostridia, *Listeria monocytogenes*, *Bacillus subtilis* and *Bacteroides melaninogenicus*.

Gram Negative

Escherichia coli, Salmonellae, Shigellae, Neisseria, *Proteus mirabilis*, *Haemophilus influenzae* (some strains), Brucellae, Klebsiella species, *Treponema pallidum* and actinomycetes.

Pharmacokinetics:

Cephalexin is almost completely absorbed from the gastrointestinal tract. If cephalexin is taken with food, absorption may be delayed, but the total amount absorbed is not appreciably altered. It is widely distributed in the body but does not enter the cerebrospinal fluids in significant quantities. It is not metabolised. About 80% or more of a dose is excreted unchanged in the urine.

DOSAGE AND ADMINISTRATION:

For oral administration only.

Adult:

Many infections in adults will respond to oral dosage of 1g to 2g per day in divided doses; however, for most infections, the following simple scheme will be found satisfactory: Adult and children over 12 years: 500mg three times daily. To aid compliance, especially in ambulatory patients, the daily dosage may be given in two equal doses, e.g. 1g twice daily in adults with urinary tract infections. For severe or deep seated infections, especially when less sensitive organisms are involved, the dosage should be increased to 1g three times daily or 1.5g four times daily.

Children:

Normal recommended dose for children:

25 – 60mg/kg/day.

For chronic, severe or deep seated infections, this should be increased to 100mg/kg/day (maximum 4g/day).

0 to 1 year : 25 to 60mg/kg/day.
1 to 2 years : 62.5 to 125mg four times daily or 125 to 250mg twice daily.
3 to 6 years : 125 to 250mg four times daily or 250 to 500mg twice daily.
7 to 12 years : 250 to 500mg four times daily or 500mg to 1g twice daily.

Duration of Treatment:

For most acute infections, treatment should continue for at least two days after signs have returned to normal and symptoms have subsided, but in chronic, recurrent or complicated urinary tract infections, treatment for two weeks (giving 500mg four times daily) is recommended.

The standard recommended dosage should be halved for patients with severe renal impairment (creatinine clearance < 10ml/min). The maximum recommended dosages (i.e. adults 6g/day, children 4g/day) should be reduced by 50% in mild, 75% in moderate and 87.5% in severe renal failure. Adult patients receiving intermittent dialysis should be given an additional 500mg cephalexin after each dialysis, i.e. total dosage up to 1g on that day. Children should receive an additional 8mg per kg.

Direction for mixing: Shake bottle well to loosen granules. Remove cap and Dose-Master™ adapter. Then, add some water to mix with the granules. After that, shake and top up to 60ml / 100ml mark. Place the Dose-Master™ adapter and cap. Shake the bottle well to mix the medicine properly.

CONTRAINDICATION:

Contraindicated in patient hypersensitive to cephalosporin.

PRECAUTIONS:

Cephalexin should be used with caution for patient with penicillin sensitivity. False positive urinary glucose and false positive Combs' test have been found during the treatment of Cephalexin. Patients with renal impairment should be given with caution. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cephalexin, and may range from mild to life threatening. Therefore, it is important to consider this diagnosis in patients with diarrhoea subsequent to the administration of cephalexin. 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.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Axcel Cephalexin-250 Suspension, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactams agents. If an allergic reaction occurs, Axcel Cephalexin-250 Suspension must be discontinued immediately and appropriate alternative therapy instituted.

Use In Pregnancy & Lactation:

Cephalexin is widely distributed in the body. It crosses the placenta and small quantities are found in the milk of nursing mother. Caution should be taken while given to pregnant women and nursing mothers.

SIDE EFFECTS:

The most common side effects of cephalexin are generally gastrointestinal disturbances and hypersensitivity reactions, including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness and anaphylaxis.

DRUG INTERACTIONS:

Cephalexin decreases the efficacy of oestrogen-containing oral contraceptives. The concomitant use of probenecid will reduce the excretion of cephalexin; nephrotoxic drug such as aminoglycoside antibiotic-gentamicin may increase the risk of kidney damage with cephalexin. Concomitant use with loop diuretic-frusemide may enhance nephrotoxicity.

OVERDOSAGE AND TREATMENT:

There is no effect would be expected due to overdosage. Overdosage has not been reported as a problem when Cephalexin is given by mouth. It can be removed by haemodialysis and peritoneal dialysis.

STORAGE:

Keep container well closed. Store below 30°C, until reconstituted. After reconstitution, refrigerate between 2°C to 8°C and use within 7 days.

KEEP OUT OF REACH OF CHILDREN.
JAUHI DARI KANAK-KANAK.

PACK QUANTITIES:

Available in amber glass bottle of 60ml & 100ml.

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

MAL16035027AZ

Manufactured By & Product Registration Holder :



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