Uphalexin Capsule 500mg
Uphalexin Capsule 250mg

COMPOSITION

Each capsule contains:
Uphalexin Capsule 500mg:
Cephalexin Monohydrate equivalent to Cephalexin 500mg
Uphalexin Capsule 250mg:
Cephalexin Monohydrate equivalent to Cephalexin 250mg

DESCRIPTION

Uphalexin Capsule 500mg: Pink/purple hard gelatin capsule, size 0
Uphalexin Capsule 250mg: Pink/Ruby red hard gelatin capsule, size 2

INDICATIONS

Treatment of the following infections when caused by susceptible strains of the designated micro-organisms.
- Respiratory Tract Infections caused by S.pneumoniae and group A - Haemolytic streptococci.
- Otitis media due to S.pneumoniae, H.influenzae, staphylococci and/or M.catarrhalis
- Bone infection caused by staphylococci and/or P.mirabilis
- Genitourinary Tract Infections, including acute prostatitis, caused by E.coli, P. mirabilis and Klebsiella spp.
- Dental infection caused by staphylococci and/or streptococci

INSTRUCTION TO USE

May be taken without regard to meals. Capsules to be taken with a glass of water.

PHARMACODYNAMICS

Cephalexin is bactericidal; its action depending on its ability to bind penicillin-binding proteins located in bacterial cytoplasmic membranes. Cephalexin inhibits synthesis of bacterial septum and cell wall probably by acylation of transpeptidases enzymes. These enzymes are responsible for the cross linking of peptidoglycan chains, which is necessary for the bacterial cell wall strength and rigidity. Cell division and growth are also inhibited. Rapidly dividing bacteria are those most susceptible to the action of cephalexin.

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

Cephalexin is administered orally.

Adults: 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 may be 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

Children: The usual recommended daily dosage for children is 25-50mg/kg (10-20mg/lb) in divided doses. For skin and soft tissue infections, streptococcal pharyngitis, and mild, uncomplicated urinary tract infections, the total daily dose may be divided and administered every 12 hours. For most infections, the following schedule is suggested
- Children 5 years and over: 250mg every 8 hours

In severe infections, the dosage may be doubled. 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

CONTRAINDICATIONS

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 diarrhea subsequent to the administration of cephalexin. Prolonged use of cephalexin may result in the overgrowth of nonsusceptible organisms. Careful observation of the patients 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 Uphalexin Capsule, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenams or other beta-lactam agents. If an allergic reactions occurs, Uphalexin Capsule must be discontinued immediately and appropriate alternative therapy instituted.

USE IN PREGNANCY AND 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

Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhoea, 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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

There are no effects on ability to drive or to operate machinery.

STORAGE

Keep container well closed. Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

170mm(w) x 210mm (h)

Black 100%

PACK QUANTITIES

Uphalexin Capsule 500mg: blister pack of 10x10's
Uphalexin Capsule 250mg: blister pack of 10x10's

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

Product Registration Holder:
Duopharma Marketing Sdn. Bhd.
Lot No. 2, 4, 6, 8 & 10,Jalan P/7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor, Malaysia.

Manufacturer:
Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

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Black 100%