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
Other excipients are magnesium stearate, lactose, purified talc and sodium lauryl sulphate.
Gelatin capsule shell:
Body - D&C red 28, FD&C blue 1, FD&C yellow 6, gelatin and titanium dioxide.
Cap - azorubine, FD&C blue 1, gelatin and quinoline yellow.

DESCRIPTION

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

INDICATIONS

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

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.

Cephalexin is active against the following micro-organisms in vitro:
Beta-haemolytic streptococci
Staphylcocci, including coagulase-positive, coagulase-negative and penicillinase-pro+ ducing 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 in vitro methods, staphylococci exhibit cross-resistance between cephalexin and methicillin-type antibiotics.

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. The half-life is approximately 60 minutes in patients with normal renal function. Haemodialysis and peritoneal dialysis will remove cephalexin from the blood.

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 4 g/day.

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.

170mm(w) x 210mm (h)

Black 100%

Acute generalised exanthematous pustulosis (AGEP) has been reported in association with cefalexin 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, cefalexin 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 AND LACTATION

Cephalexin is widely distributed in the body. It crosses the placenta and small quantities are found in the milk of nursing mother. The excretion of cephalexin in human breast milk increased up to 4 hours following a 500 mg dose. The drug reached a maximum level of 4 micrograms/ml, then decreased gradually and had disappeared 8 hours after administration. 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 (including nausea, vomiting and diarrhoea). Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, trainsient 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 subsided upon discontinuation of the drug, although in some cases, supportive therapy may be necessary.

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

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

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

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.

As cephalosporins like cefalexin are only active against proliferating microorganisms, they should not be combined with bacteriostatic antibiotics.

Combined use of cephalosporins and oral anticoagulants may prolong prothrombin time.

A potential interaction between cefalexin and metformin may result in an accumula+ tion of metformin and could result in fatal lactic acidosis.

Hypokalaemia has been described in patient taking cytotoxic drugs for leukaemia when they were given gentamicin and cefalexin.

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.

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

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

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

STORAGE

Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES

Uphalexin Capsule 500mg: blister pack of 10x10's
Uphalexin Capsule 250mg: blister pack of 10x10's
Not all product strengths may be available locally

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.

Duopharma (Singapore) Pte. Ltd.
25, International Business Park,
#03-53, German Centre, Singapore 609916

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

Revision Date: April 2022

170mm(w) x 210mm (h)

Black 100%