DYNALEXIN DRY SYRUP

	DESCRIPTION	CONTENT
DYNALEXIN DRY SYRUP 125MG/5ML MAL07031083AZ	White coloured powder. Light green in colour suspension, opaque and smooth with vanilla flavour on adding water.	Each 5 ml of the reconstituted suspension contains: Cephalexin Monohydrate equivalent to Cephalexin ..... 125 mg Colouring agents: Green S + Brilliant Blue Preservative: Sodium Benzoate 0.1% w/v
DYNALEXIN DRY SYRUP 250MG/5ML MAL07031092AZ	White coloured powder. Light green in colour suspension, opaque and smooth with vanilla flavour on adding water.	Each 5 ml of the reconstituted suspension contains: Cephalexin Monohydrate equivalent to Cephalexin ..... 250 mg Colouring agents: Green S + Brilliant Blue Preservative: Sodium Benzoate 0.1% w/v

DIRECTION FOR MIXING:

1. Shake well to loosen powder.
2. Add approximately half the final volume (30 ml or 50 ml) freshly boiled and cooled water and shake.
3. Add more water until the final volume mark (60 ml or 100 ml) is reached and shake well.

   To be used within 7 days of mixing.

PHARMACODYNAMICS:

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*
- *Proteus mirabilis*
- *Klebsiella* species
- *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 pneumoniae* 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 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 32mg/l, respectively, were obtained at 1 hour. Measurable 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 were excreted unchanged in the urine within 8 hours. During this period, peak urine concentrations following the 250mg, 500mg, and 1g doses were approximately 1,000, 2,200, and 5,000mg/l, respectively.
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 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 are excreted in the urine within 6 hours. No accumulation is seen with dosages above the therapeutic maximum of 4g/day.
The half-life may be increased in neonates due to their renal immaturity, but there is no accumulation when given at up to 50mg/kg/day.

INDICATIONS:

Cephalexin is a semi-synthetic cephalosporin antibiotic for oral administration.
It is indicated in the treatment of the following infections due to susceptible microorganisms:

- Respiratory tract infections
- Otitis media
- Skin and soft tissue infections
- Bone and joint infections
- Genito-urinary tract infections, including acute prostatitis
- Dental infections

RECOMMENDED DOSAGE:

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 (see section **PRECAUTIONS/WARNINGS**).
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 under 5 years: 125mg every 8 hours.
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:
Cephalexin is contraindicated in patients with known allergy to the Cephalosporin group of antibiotics.

PRECAUTIONS/WARNINGS:
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 anaphylaxis) to both drugs.
Pseudomembranous colitis has been reported with virtually all broad-spectrum 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 mothers have received cephalosporin antibiotics before parturition, it should be recognised 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.
This preparation contains Sodium Metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.
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 Dynalexin Dry Syrup, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta lactam agents. If an allergic reaction occurs, Dynalexin Dry Syrup must be discontinued immediately and appropriate alternative therapy instituted.

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 C_{max} 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.

PREGNANCY AND LACTATION:
Usage in pregnancy: Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing for the pregnant patient.
Usage in nursing mothers: 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 micrograms/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/ADVERSE REACTIONS:
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.
Other: These have included genital and anal pruritus, 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.

SYMPTOMS AND TREATMENT OF OVERDOSE:
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, gastrointestinal decontamination should not be necessary.
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.

PACKING/PACK SIZE(S):
Plastic bottles of 60 ml and 100 ml.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
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