KEFLEX®* (cephalexin monohydrate)

DESCRIPTION

KEFLEX (cephalexin monohydrate, LILLY) is a semisynthetic cephalosporin antibiotic for oral administration. It is 7-(D-α-amino-α-phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid, monohydrate.

PRESENTATION▲

Formen 3

- KEFLEX 500 mg: - tablets each equivalent to 500 mg cephalexin.
  - capsules each equivalent to 500 mg cephalexin.
- KEFLEX 250 mg: - tablets each equivalent to 250 mg cephalexin.
  - capsules each equivalent to 250 mg cephalexin.
  - granules to obtain either 60 ml or 100 ml suspensions, equivalent to 250 mg cephalexin per tea-spoon (= 5 ml).
- KEFLEX 125 mg: - granules to obtain either 60 ml or 100 ml suspensions, equivalent to 125 mg cephalexin per tea-spoon (= 5 ml).

INDICATIONS

Cephalexin is indicated in the treatment of the following infections due to susceptible micro-organisms: respiratory tract infections; otitis media; skin and soft tissue infections; bone and joint infections; genito-urinary infections, including acute prostatitis; dental infections.
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. When tested by *in vitro* methods, staphylococci exhibit cross-resistance between cephalexin and methicillin-type antibiotics.

DOSAGE AND ADMINISTRATION

KEFLEX is administered orally.
Adults: The adult dosage ranges from 1-4 g daily in divided doses; most infections will respond to a dosage of 500 mg every 8 hours. For skin and soft tissue infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the usual dosage is 250 mg every 6 hours, or 500 mg every 12 hours. For more severe infections or those caused by less susceptible organisms, larger doses may be needed. If daily doses of KEFLEX greater than 4 g 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 PRECAUTIONS).
Children: The usual recommended daily dosage for children is 25-50 mg/kg 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: 125 mg every 8 hours.
Children 5 years and over: 250 mg 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 100 mg/(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.

CONTRA-INDICATIONS

Cephalexin is contra-indicated in patients with known allergy to the cephalosporin group of antibiotics.

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, semisynthetic 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.
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 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 exercised when cephalexin is administered to a nursing woman.

PRECAUTIONS

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.

ADVERSE REACTIONS

Gastro-intestinal - 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.
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. Eosinophilia, neutropenia, thrombocytopenia, and slight elevations in AST and ALT have been reported.

OVERDOSAGE

Treatment of overdosage - 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, pentoneal 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 3.5 g of cephalexin in a day. Treatment has been supportive (fluids) and no sequelae have been reported.

STORAGE

Capsules and tablets - Keep containers tightly closed.
Suspensions - After mixing, KEFLEX suspensions should be stored in a cool place (6°-15°C) or in a refrigerator (0°-6°C) and be used within 10 days. Where dilution is unavoidable, Syrup BP should be used after the suspension has been prepared according to the manufacturer's instructions.

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▲ All presentations may not be available in all countries.

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