



PRESCRIBING INFORMATION

Keflex (cephalexin monohydrate, Lilly) is a semi-synthetic cephalosporin antibiotic intended for oral administration. It is 7-[D- α -amino- α -phenylacetamido]-3-methyl-3-cephem-4-carboxylic acid, monohydrate.

ACTIONS

Microbiology - In vitro tests demonstrate that the cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. Keflex is active against the following organisms in vitro:

Beta-hemolytic and others streptococci (many strains of enterococci; e.g. *Streptococcus faecalis*, are resistant)

Staphylococci, including coagulase-positive coagulase-negative, and penicillinase-producing strains (a few strains of staphylococci are resistant to cephalixin)

Diplococcus pneumoniae

Escherichia coli

Proteus mirabilis

Klebsiella pneumoniae

Many strains of *Hemophilus influenzae*

Keflex is not active against most strains of *Proteus morgani* or *Proteus vulgaris*. It has no activity against *Pseudomonas* species. Keflex resists destruction by penicillinase, but is sensitive to B-lactamase produced by certain gram-negative bacilli.

Human Pharmacology - Keflex is rapidly absorbed after oral administration. Following doses of 250 and 500 mg., average peak serum levels of approximately 9 and 18 mcg. per ml. respectively were obtained at one hour. Measurable levels were present six hours after administration. Over 90 percent of the drug is excreted unchanged in the urine within eight hours. Peak urine concentrations are approximately 1,000 mcg. per ml. during this period following a 250-mg. dose.

INDICATIONS

Keflex is indicated in the treatment of infections of the respiratory tract, genito-urinary tract, skin, and soft tissues when the infection is caused by susceptible organisms.

CONTRAINDICATIONS

Keflex is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

In penicillin-sensitive patients, cephalosporin antibiotics should be used with great caution. There is clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins. Instances of patients who have had severe reactions to both drugs (including fatal anaphylaxis after parenteral use) have been reported. As with oral penicillins, immediate and severe reactions are much less likely to occur after administration of Keflex, an oral cephalosporin.

Any patient who has demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously and then only when absolutely necessary. No exception should be made with regard to Keflex.

PRECAUTIONS

As is the case with all new drugs, patients should be followed carefully so that any side-effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to Keflex occurs, the drug should be discontinued and the patient treated with the usual agents (e.g. epinephrine, antihistamines, pressor amines, or corticosteroids).

Prolonged use of Keflex will 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.

Like other potent antibacterial agents excreted by the kidney, Keflex should be administered with caution in the presence of impaired renal function.

Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

If Keflex is to be used for long term therapy, periodic monitoring of hematology, renal and hepatic functions should be done.

Safety of this product for use during pregnancy has not been established.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy; e.g. the incision and drainage of abscesses.

Keflex may produce a false-positive reaction for glucose in the urine with Benedict's or Fehling's solution or with Clinitest tablets, but not with Tes-Tape (urine sugar analysis paper, Lilly).

ADVERSE REACTIONS

Gastro-intestinal - The most frequent side-effect is diarrhea. In the majority of patients, it was not severe enough to warrant cessation of therapy. Nausea and vomiting have also occurred. Dyspepsia and abdominal pain have been reported.

Hypersensitivity - Allergies (in the form of rash and urticaria) have occurred. These reactions usually subsided upon discontinuation of the drug.

Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, and headache.

Eosinophilia has been reported; approximately 13% of patients demonstrated an increase above 4%.

Leucopenia and neutropenia have been observed in a few patients.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

No information is available on the treatment of overdose with Keflex. There is no specific antidote.

DOSAGE AND ADMINISTRATION

Keflex is administered orally. The adult dosage ranges from 1 to 4 Gm. daily in divided doses. The usual adult dose is 250 mg every six 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 Gm. are required, parenteral cephalosporins, in appropriate doses should be considered.

The recommended daily dosage for children is 25 to 50 mg per Kg. divided into four doses.

Child's Weight	Keflex Suspension	
	125 mg./5 ml.	250 mg./5 ml.
10 Kg (22 lb.)	½ to 1 tsp. q.i.d.	
20 Kg (44 lb.)	1 to 2 tsp. q.i.d.	½ to 1 tsp. q.i.d.
40 Kg (88 lb.)	2 to 4 tsp. q.i.d.	1 to 2 tsp. q.i.d.

In severe infections, the dosage may be doubled.

In the treatment of streptococcus infections, a therapeutic dosage of Keflex should be administered for at least ten days.

HOW SUPPLIED

Pulvules Keflex, equivalent to 250 mg cephalixin (No. 402) are supplied in bottles of 50. *Identif-code H69.*

Keflex 500 mg Tablets (T. 1895), equivalent to 500 mg cephalixin, are supplied in bottles of 50. *Identif-code U49.*

Keflex Oral Suspension (M-201) equivalent to 125 mg cephalixin per 5 ml teaspoon, in 100 ml - size packages. Bubble gum flavour. *Identif-code W21.*

Keflex Oral Suspension (M-202) equivalent to 250 mg cephalixin per 5 ml teaspoon, in 100 ml size packages. Peach coloured granules, bubble-gum flavour. *Identif-code W68.*

the lungs during the tonic phase and in the clonic phase it is unlikely that more will be inspired than will exchange with the dead space. Whether the tongue is obstructing the airway or not is, therefore, irrelevant.

If bitten, the tongue is painful for a few days, but this is only a temporary problem because the tongue is extremely vascular and prone to excellent healing.

When the seizure is over and the patient is recovering in the flaccid phase, he may be turned on his side; with fingers placed behind the angle of the jaw it may be possible to push the jaw forward and upward, thereby pulling the tongue forward and relieving any airway obstruction the tongue may have produced by falling back. To attempt to separate the jaws is to court disaster from a broken tooth that will very possibly be inhaled, with the almost inevitable sequela of a lung abscess.

I therefore suggest that to attempt to push a wooden tongue depressor between the teeth is futile and to insert a metal jaw-separator is dangerous and unnecessary in a patient having a grand mal seizure.

The seizure is best managed by moving the patient from any dangerous situation in which he may have his attack, turning him on his side after the tonic and clonic phases are over, and pulling the jaw forward and upward until such time as spontaneous respiration and gag and cough reflexes are re-established. Nothing should be placed in the mouth.

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Medic-Alert bracelets

To the editor: Medic-Alert has over 100 000 bracelet wearers in Canada. Dr. Rabinovitch's patient (*Can Med Assoc J* 111: 1191, 1974) is the only one who has presented with this complaint. The victim, however, may be the 1 in 20 000 who is allergic to stainless steel. These are exceptions. For all other Medic-Alert members we insist that they never remove their bracelets. Indeed, most hospitals have agreed not to do this even during an operation. The sister hook is designed to make it almost impossible for the wearer to remove his own bracelet. We also advise that enough links be cut from the chain so that it fits snugly. Such an adjustment could help Dr. Rabinovitch's patient and eliminate any need for removal.

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