KEFLEX® (cephalexin) capsules, for oral use

Initial U.S. Approval: 1971

INDICATIONS AND USAGE

KEFLEX is a cephalosporin antibacterial drug indicated for the treatment of the following infections caused by susceptible isolates of designated bacteria:

- Respiratory tract infection (1.1)
- Otitis media (1.2)
- Skin and skin structure infections (1.3)
- Bone infections (1.4)
- Genitourinary tract infections (1.5)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of KEFLEX and other antibacterial drugs, KEFLEX should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. (1.6)

DOSAGE AND ADMINISTRATION

Adults and patients at least 15 years of age

The usual dose is 250 mg every 6 hours, but a dose of 500 mg every 12 hours may be administered. (2.1)

Pediatric patients (over 1 year of age)

- Otitis media: 75 to 100 mg/kg in equally divided doses every 6 hours. (2.2)
- All other indications: 25 to 50 mg/kg in equally divided doses. (2.2)
- In severe infections: 50 to 100 mg/kg may be administered in equally divided doses. (2.2)

Duration of therapy ranges from 7 to 14 days depending on the infection type and severity. (2)

Dosage adjustment is required in patients with severe and end stage renal disease (ESRD) defined as creatinine clearance below 30 mL/min. (2.3)

DOSE FORMS AND STRENGTHS

Capsules: 250 mg, 500 mg and 750 mg (3)

CONTRAINdications

Patients with known hypersensitivity to cephalexin or other members of the cephalosporin class of antibiotic drugs. (4)

WARNINGS AND PRECAUTIONs

- Serious hypersensitivity (anaphylactic) reactions. Prior to use, inquire regarding history of hypersensitivity to beta-lactam antibacterial drugs. Discontinue the drug if signs or symptoms of an allergic reaction occur and institute supportive measures. (5.1)
- Chloramphenicol-induced jaundice (CARI): Evaluate if diarrhea occurs. (5.2)
- Direct Coombs’ Test Seronegativity: If anemia develops during or after cephalosporin therapy, evaluate for drug-induced hemolytic anemia. (5.3)
- Seizure Potential: Use lower dose in patients with renal impairment. (5.4)

ADVERSE REACTIONS

The most common adverse reactions associated with KEFLEX include diarrhea, nausea, vomiting, dyspepsia and abdominal pain. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Pharmaceuticals, LLC at (414) 434-6604 Monday-Friday 9am-5pm EST, or to FDA at 1-800-FDA-1088.

DRUG INTERACTIONS

- Metformin: increased metformin concentrations. Monitor for hypoglycemia. (7.1)
- Probenecid: The renal excretion of KEFLEX is inhibited by probenecid. Co-administration of probenecid with KEFLEX is not recommended. (7.2)
- Administration of KEFLEX may result in a false-positive reaction for glucose in the urine. (7.3)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 10/2015

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FULL PRESCRIBING INFORMATION 1 INDICATIONS AND USAGE 1.1 Respiratory Tract Infections KEFLEX is indicated for the treatment of respiratory tract infections caused by susceptible isolates of Streptococcus pneumoniae and Staphylococcus aureus.

1.2 Otitis Media KEFLEX is indicated for the treatment of otitis media caused by susceptible isolates of Streptococcus pneumoniae, Haemophilus influenzae, Staphylococcus aureus, Staphylococcus pyogenes, and Moraxella catarrhalis.

1.3 Skin and Skin Structure Infections KEFLEX is indicated for the treatment of skin and skin structure infections caused by susceptible isolates of the following Gram-positive bacteria: Staphylococcus aureus and Staphylococcus pyogenes.

1.4 Bone Infections KEFLEX is indicated for the treatment of bone infections caused by susceptible isolates of Staphylococcus aureus and Proteus mirabilis.

1.5 Genitourinary Tract Infections KEFLEX is indicated for the treatment of genitourinary tract infections, including acute prostatitis, caused by susceptible isolates of Escherichia coli, Proteus mirabilis, and Klebsiella pneumoniae.

1.6 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of KEFLEX and other antibacterial drugs, KEFLEX should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. When culture and susceptibility information is available, it should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Adults and Pediatric Patients at Least 15 years of age

The usual dose of oral KEFLEX is 500 mg every 6 hours, but a dose of 500 mg every 12 hours may be administered. Treatment is administered for 7 to 14 days.

For more severe infections larger doses of oral KEFLEX may be needed, up to 4 grams daily in two to four equally divided doses.

2.2 Pediatric Patients (over 1 year of age)

The recommended total daily dose of oral KEFLEX for pediatric patients is 25 to 50 mg/kg given in equally divided doses for 7 to 14 days. In the treatment of H. hemolytic streptococcal infections, duration of at least 10 days is recommended. In severe infections, a total daily dose of 50 to 100 mg/kg may be administered in equally divided doses.

For the treatment of otitis media, the recommended daily dose is 75 to 100 mg/kg given in equally divided doses.

2.3 Dosage Adjustments in Adult and Pediatric Patients at Least 15 years of Age with Renal Impairment

Administer the following dosing regimens for KEFLEX to patients with impaired renal function (see Warnings and Precautions (4) and Use in Specific Populations (8.6)).

Table 1. Recommended Dose Regimen for Patients with Renal Impairment

<table>
<thead>
<tr>
<th>Renal function</th>
<th>Dose regimen recommendation</th>
<th>Creatinine clearance</th>
<th>Dose adjustment</th>
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</thead>
<tbody>
<tr>
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<td>15 to 29 mL/min</td>
<td>No dose adjustment</td>
<td>Maximum daily dose should not exceed 1 g</td>
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<tr>
<td>Creatinine clearance 15 to 29 mL/min</td>
<td>not yet on dialysis*</td>
<td>250 mg, every 8 hours or every 12 hours</td>
<td>250 mg, every 24 hours</td>
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<tr>
<td>Creatinine clearance</td>
<td>not yet on dialysis*</td>
<td>250 mg, every 48 hours or every 60 hours</td>
<td>250 mg, every 24 hours</td>
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Note: There is insufficient information to make dose adjustment recommendations in patients on hemodialysis.

3 DOSAGE FORMS AND STRENGTHS

500 mg capsules: A white to light yellow powder filled into an opaque white and opaque dark green capsule that is imprinted with KEFLEX 500 mg in edible white ink on the white body.

500 mg capsules: A white to light yellow powder filled into an opaque light green and opaque dark green capsule that is imprinted with KEFLEX 500 mg in edible black ink on the light green body.

250 mg capsules: A white to light yellow powder filled into an opaque dark green and opaque dark green capsule that is imprinted KEFLEX 250 mg in edible white ink on the dark green body.

4 CONTRAINDICATIONS

KEFLEX is contraindicated in patients with known hypersensitivity to cephalexin or other members of the cephalosporin class of antibacterial drugs.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reaction

Allergic reactions in the form of rash, urticaria, angioedema, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been reported with the use of KEFLEX. Before therapy with KEFLEX is instituted, inquire whether the patient has a history of hypersensitivity reactions to cephalosporins, penicillins, or other drugs. Cross-hypersensitivity among beta-lactam antibiotic drugs may occur in up to 10% of patients with a history of penicillin allergy.

12.3 Pharmacokinetics

12.4 Microbiology

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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8.1 Pregnancy

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Reproduction studies have been performed on mice and rats using oral doses of cephalosporin monohydrate 0.6 and 1.5 times the maximum daily human dose. No evidence of harm to the fetus has been observed.

8.2 Nursing Mothers

Cefalexin is excreted in human milk. Caution should be exercised when KEFLEX is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of KEFLEX in pediatric patients was established in clinical trials for the dosages described in the dosage and administration section (see Dosage and Administration (2.3)).

8.5 Geriatric Use

Use in elderly patients is similar to that described under the Keftacin® product. The clinical relevance of these differences in responses between the elderly and younger patients is not known.

This drug is substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection (see Warnings and Precautions (4.4)).

8.6 Renal Impairment

KEFLEX should be administered with caution in the presence of impaired renal function. In patients with impaired renal function, the usual dose of KEFLEX should be given; however, the dosage interval should be increased. If the creatinine clearance is less than 30 ml/min, the usual dose of KEFLEX should be given; however, the dosage interval should be increased. If the creatinine clearance is less than 30 ml/min, the usual dose of KEFLEX should be given; however, the dosage interval should be increased. If the creatinine clearance is less than 30 ml/min, the usual dose of KEFLEX should be given; however, the dosage interval should be increased. If the creatinine clearance is less than 30 ml/min, the usual dose of KEFLEX should be given; however, the dosage interval should be increased. If the creatinine clearance is less than 30 ml/min, the usual dose of KEFLEX should be given; however, the dosage interval should be increased. If the creatinine clearance is less than 30 ml/min, the usual dose of KEFLEX should be given; however, the dosage interval should be increased.
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### Schiemann Design

3. Probedruck

29.08.2011

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