KENDROX

کینڈروکس

(Cefadroxil)

(سیفاڈروکسل)

Capsules
500mg & 1000mg

Dry Suspension
125mg/5ml & 250mg/5ml

DESCRIPTION:
KENDROX contains cefadroxil, a semisynthethetic cephalosporin antibiotic intended for oral administration.

COMPOSITION:
KENDROX Capsule 1000mg
Each capsule contains:
Cefadroxil Monohydrate equivalent to Cefadroxil.....1000mg
KENDROX Capsule 500mg
Each capsule contains:
Cefadroxil Monohydrate equivalent to Cefadroxil.....500mg
KENDROX 125mg/5ml dry suspension
After reconstitution each 5 ml Suspension contains:
Cefadroxil Monohydrate equivalent to Cefadroxil.....125mg
KENDROX 250mg/5ml dry suspension
After reconstitution each 5 ml Suspension contains:
Cefadroxil Monohydrate equivalent to Cefadroxil.....250mg

CLINICAL PHARMACOLOGY:
Cefadroxil is rapidly absorbed after oral administration. Following single doses of 500mg and 1g, average peak serum concentrations were approximately 16 and 28 p/mL, respectively Measurable serum levels were present 12 hours after administration. Absorption charctenstics are not different between fasted and nontested subjects. Over 90% of the drug is excreted unchanged in the urine within 24 hours. The elimination on half-life is about 2 hours. Peak urine concentrations are approximately 1800 µ/mL during the period following a single 500mg oral dose. Increases In dosage generally produce a proportionate increase in cefadroxil urinary concentration. The urine antibiotic concentration, following a 1g(1000mg) dose, was maintained well above the MIC of susceptible urinary pathogens for 20 to 22 hours.

Microbiology:
In vitro tests demonstrate that the cephalosporins are bactericidal because of their Inhibition of Cell- wall synthesis.

KENDROX is active against the following organism Vitro:
Beta-hemolytic streptococci
Streptococcus pneumoniae
Staphylococci, including coagulase-positive, cosgulase-negative, and penicillinase-producing strains
Escherichia soli
Proteus mirabilis
Klebsiella species

Moraxella (Branhamella) catarrhalis
Becteroides species (excluding Bacteroides fregilio) Other strains of sensitive gram-negative organisms include some strains of Haemophilus influenzae, Salmonella species and Shigella species. Note: Most strains of Enterococcus (Enterococcus faecalis and faecium) are resistant to KENDROX. KENDROX is not active against most strains of Enterobacter species, Morganella rnorganii (fomerly Proteus morganii), and Proteus vulgaris. It has no activity against Pseudomoras species and Acinetobacter calcoaceticus (formerly Mime and Herellea species).

Disc Susceptibility Tests
Quantitative methods that require measurement of zone diameters give the most precise estimates of antibiotic susceptibility. One recommended laboratory procedure uses a cephalosporin class disc for testing susceptibility: interpretations correlate zone diameters of this disc test with MIC values for KENDROX. With this procedure, a report of "susceptible" indicates that the infecting organism is likely to respond to therapy. A report of resistant" indicates that the infecting organism is not likely to respond to therapy. A report of intermediate susceptibility suggests that the organism would be susceptible if the infection is confined to an area where adequate drug concentrations can be achieved. for example, the urinary tract.

INDICATIONS
KENDROX is indicated for the treatment of the following infections when due to susceptible microorganisms:
Upper and lower respiratory infections
Skin and soft tissue infection
Genitourinary tract infections
Other infections: osteomyelitis and septic arthritis
Note: Culture and susceptibility tests should be initiated prior to and during therapy.
Renal function studies should be performed when indicated. Surgical procedures should be performed when indicated.
Note: Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. KENDROX is generally effective in the eradication of streptococci from the oropharynx. However date establishing the efficacy of KENDROX for the prophylaxis of subsequent rheumatic fever are not available.

CONTRAINDICATIONS
KENDROX is contraindicated in patients with known allergy to the cephalosporin group of anti-bka or to any component of the formulation.

WARNINGS
Before therapy with KENDROX is instilled, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to KENDROX, odor cephalosporins, particles, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-sensidvmy among beta-lactam antibiotics has been clearly documented and may occur in upto to 10% of patients with a history of penicillin allergy. if an allergic reaction to KENDROX occurs, discontinue the drug. Serious acute hypersensitivity reactions may require emergency treatment measures. Pseudomembranous colitis has been reported with nearly all antibacterial agents, and may range from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents. After the diagnosis colitis has been established, therapeutic measures should be initiated.

PRECAUTIONS:
General
KENDROX should be used with caution in the presence of impaired renal function.
(See DOSAGE AND ADMINISTRATION for dosage guidelines). In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy Prolonged use of KENDROX may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic 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 recognized that a positive Coombs' test may be due to the drug.

KENDROX should be prescribed with caution in Individuals with a history of gastrointestinal disease. particularly colitis.Carcinogenesis, Mutagenesis and Impairment of Fertility No tong-term studies have been performed to determine carcinogenic potential. No genetic toxicity tests have been performed.

Pregnancy
Reproduction studies have been performed in mice and rats at doses up to 11 times are human dose and have revealed no evidence of impaired fertili or harm to the fetus due to cefadroxil.

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

Nursing Mothers
Cefadrexil is distributed in to breast milk: therefore, this drug should be used with caution in nursing women.

ADVERSE EVENTS
The adverse events observed with cafaxroxil are similar to those observed with other cephalosporins Gastrointestinal Symptoms of pseudomembranous colitis can appear during or after antibiotic treatment. Nausea, vomiting, and dyspepsia have been reported rarely. Administration with food decreases nausea.

Diarrhea has also occurred.
Hypersensitivity - In common with other cephalosporins, allergic reactions, including priapus, rash, utlcarta, and agicedema have been observed. These reactions usually shakled upon abconfim aution of the drug Erythema multiforme, Stevens-Johnson syndrome, Serum sickness, and anaphylaxis have been reported rarely.
Other reactions have included genital pruritus. genital candidiasis, vaginitis, moderate transient neutropenia, fever, and elevations in serum transaminase. In common with other cephelosporins, agranulocytosis, thrombocytopenia, and arthralgia have been rarely reported. During post rnarking experience, hepatic dysfunction, including cholestasis has been reported. and rare reports of idiosyncratic hepatic failure have been received; because of the uncontrolled nature of these spontaneous reports, a causal relationship to cefadroxil has not been established.

OVERDOSAGE
Data from a study of children under six years of age who had Ingested a maximum of 250 mg/kg of penicillin or a cephalosporin derivative suggested teat ingestion of less then 250 mg/kg of cephalosporins (i.e., 5 to 10 times recommended dose) is not associated with significant out comes.
No treatment is required other than general support and observation. During the 72 hours evaluation period, most of the children remained asymptomatic. Gastrointestinal disturbances and a rash were reported in some children. For amount greater than 250 mg/kg, induce gastric emptying (emesis induction or gastric lavage). For information on removal of drug by hemodialyais, see Dosage end Administration.

DOSAGE AND ADMINISTRATION
KENDROX is acid stable and may be administered orally without regard to meals. Administration with food may be helpful in diminishing potential gastrointestinal complaints occasionally associated with oral cephalosporin therapy.

Adults
Urinary Tract Infections
For uncomplicated lower urinary tract infections (i.e., cystitis) the usual dosage is 1 or 2 g Per day in a single dose or in two equally divided doses. For all other urinary tract infections the usual dosage is 2g (2000mg) per day in two equally divided doses.

Skin and Skin Structure Infections
For skin and skin structure infections the usual dosage is 1g(1000mg) per day in a single dose two equally divided dose.

Pharyngitis and Tonsillitis
Due to Group A beta-hemolytic streptococci
Treatment of Group A beta-hemolytic streptococcal pharyngitis and tonsillitis 1g(1000mg) per day in a single dose or two equally divided doses for at least ten days.

Upper and Lower Respiratory Tract infections
For mild infections the usual dosage is 1g(1000mg) per day in two equally divided doses. For moderate to severe infections the recommended dosage is 1 g to 2 g daily in two equally divided doses.

Children
The recommended dosage for children is 25 to 50 mg/kg day in two equally divided doses

(every 12 hours) as indicated. For pharyngitis, tonsillitis, and impetigo the recommended daily dosage

KENDROX ORAL SUSPENSION (dose q 12h)

Child's Weight (kg)	125mg/5mL (25 mg1mL)	250mg/5mL (50 mg1mL)
5	2.5-5 mL	
10	5-10 mL	2.5-5 mL
15	7.5-15 mL	3.75-7.5 mL
20	10 - 20 mL	5-10 mL
25	12.5-25 mL	6.25-12.5 mL

In the treatment of beta-hemolytic streptococcii infections a therapeutic dosage of KENDROX should be administered for at least 10 days. For the treatment of beta-hemolytic streptococcii pharyngitis or tonsillitis in both adults and children KENDROX may be administered in the usual daily dose either in two divided doses or a single dose.

In patients with renal impairment the dosage of cefadroxil should be adjusted according to creatinine clearance rates to prevent drug accumulation. The following schedule is suggested. In adults, the initial dose is 1g of KENDROX and the maintenance dose (based on the creatinine clearance rate) is 500 mg at the time intervals listed below.
Creatinine Clearance (mL/min/1.73 m2) Dosage Interval

0-10 36 hours
10 .25 24 hours
25.50 12 hours

Patients with creatinine clearance rates over 50 mL/min/1.73m2 may be treated as if they were patients having normal renal function.
In five adult anuric patients it was demonstrated that an average of 63% of a 1g oral dose is extracted from the body during a 6 to 8 hour hemodialysis session.

HOW SUPPLIED:
KENDROX 1000mg capsule is available in blister pack of 12's.
KENDROX 500mg capsule is available in blister pack of 10's, 12's, 20's and 30's
KENDROX 125mg/5ml & 250mg/5ml dry suspension available in glass bottle pack.

Dosage:
As directed by the physician.

Instructions:
Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

Shake Well Before Each Use (For Dry Suspension)

- خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- ہدایات: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

ہر استعمال سے پہلے اچھی طرح ہلائیں۔ (ڈرائے سسپنشن کے لئے)۔

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