Cloracef®

دار الدواء
Dar Al Dawa

Cefaclor

DESCRIPTION:
Cloracef® is cefaclor, a second generation cephalosporin. It is a broad spectrum antibiotic having bactericidal and antimicrobial activity. Particularly, it is very active against Gram-negative bacteria. It may be less affected by staphylococcal penicillinase than first generation cephalosporins.

PHARMACOLOGY:
Cefaclor is well absorbed from the gastro-intestinal tract. Doses of 250 mg and 500 mg by mouth produce peak plasma concentrations of about 7 and 13 mcg/ml respectively at 0.5 to 1 hour. Peak plasma concentration appears 0.75 to 1 hour later in the presence of food, but the total amount absorbed is unchanged. The serum half-life ranges from 0.6 to 0.9 hour. Cefaclor appears to be widely distributed in the body, it crosses the placenta and is excreted in small concentrations in breast milk. It is rapidly excreted by the kidneys, up to 85% of a dose appears unchanged in urine within 8 hours, the greater part within 2 hours. Peak concentrations of 600 and 900 mcg/ml have been reported after doses of 250 and 500 mg respectively. Probenecid delays excretion.

INDICATIONS:
Cloracef® is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:
- Otitis media caused by *S. pneumoniae, H. influenzae*, staphylococci, *S. pyogenes* (group A ß-hemolytic streptococci), and *M. catarrhalis*.
- Lower respiratory tract infections, including pneumonia, caused by *S. pneumoniae, H. influenzae, S. pyogenes* (group A ß-hemolytic streptococci), and *M. catarrhalis*.
- Upper respiratory infections, including pharyngitis and tonsillitis, caused by *S. pyogenes* (group A ß-hemolytic streptococci), and *M. catarrhalis*.
- Urinary tract infections, including pyelonephritis and cystitis, caused by *E. coli, P. mirabilis, Klebsiella spp*, and coagulase-negative staphylococci. Note: Cefaclor has been found to be effective in both acute and chronic urinary tract intections.
- Skin and skin structure infections caused by Staphylococcus aureus and *S. pyogenes* (group A ß-hemolytic streptococci).
- Sinusitis
- Gonococcal urethritis

CONTRAINDICATIONS:
Cloracef® should not be administered to patients who have shown hypersensitivity to cephalosporins.

SIDE EFFECTS:
Adverse effects considered to be related to therapy with cefaclor are listed below:
- Hypersensitivity reactions have been reported and include morbilliform eruptions, pruritus, urticaria, and positive Coombs' tests.
- Cases of serum-sickness-like reactions have been reported with the use of cefaclor.
- More severe hypersensitivity reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis have been reported rarely.
- Gastrointestinal symptoms include diarrhea.
  Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Other effects considered related to therapy included eosinophilia, genital pruritus, moniliasis or vaginitis and rarely, thrombocytopenia or reversible interstitial nephritis.
- CNS: Rarely, reversible hyperactivity, agitation, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations, and somnolence have been reported.
- Hepatic: Slight elevations of AST (SGOT), ALT (SGPT), or alkaline phosphatase values.
- Hematopoietic: As has also been reported with other ß-lactam antibiotics, transient lymphocytosis, leucopenia, and rarely, hemolytic anemia, aplastic anemia, agranulocytosis, and reversible neutropenia of possible clinical significance.
- There have been rare reports of increased prothrombin time with or without clinical bleeding in patients receiving cefaclor and coumadin concomitantly.
- Renal: Slight elevations in BUN or serum creatinine or abnormal urinalysis.
- Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

WARNINGS AND PRECAUTIONS:
- Patients intolerant to pencillin may show cross sensitivity to cephloaporins. Caution is recommended when cephalosporins are administered to patients with a history of pencillin anaphylaxis.
- Psedomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semi-synthetic penicillins, and cephalosporins), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with use of antibiotics, such colitis may range in severity from mild to life-threatening.
- General: Prolonged use of cefaclor 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.
- Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics.
- Cefaclor should be administered with caution in the presence of markedly impaired renal function. Since the half-life of cefaclor in anuria is 2.3 to 2.8 hours, dosage adjustments for patients with moderate or severe renal impairment are usually not required.
- Antibiotics, including cephalosporins, should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Drug/Laboratory Test Interactions: Patients receiving cefaclor may show a false-positive reaction for glucose in the urine.
- There have been rare reports of increased anticoagulant effect when cefaclor and oral anticoagulants were administered concomitantly.
- As with other ß-lactam antibiotics, the renal excretion of cefaclor is inhibited by probenecid.
- Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies have not been performed to determine potential for carcinogenicity or mutagenicity. Reproduction studies have revealed no evidence of impaired fertility.
- Usage in Pregnancy: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.
- Labor and Delivery: The effect on nursing infants is not known. Caution should be exercised when cefaclor is administered to a nursing woman.
- Pediatric Use: Safety and effectiveness of this product for use in infants less than 1 month of age have not been established.

DOSAGE AND ADMINISTRATION:
Cloracef® is administered orally.
Adults: The usual adult dosage is 250 mg every 8 hours. For bronchitis and pneumonia, the dosage is 250 mg administered 3 times daily. A dosage of 250 mg administered 3 times daily for 10 days is recommended for sinusitis. For more severe infections (such as pneumonia) or those caused by less susceptible organisms, doses may be doubled. Doses of 4 g/day have been administered safely to normal subjects for 28 days, but the total daily dosage should not exceed this amount.
For the treatment of acute gonococcal urethritis in males and females, a single dose of 3 g combined with probenecid, 1 g, is given.
Children: The usual recommended daily dosage for children is 20 mg/kg/day in divided doses every 8 hours. For bronchitis and pneumonia, the dosage is 20 mg/kg/day in divided doses administered 3 times daily. In more serious infections, otitis media, and infections caused be less susceptible organisms, 40 mg/kg/day in divided doses are recommended, with a maximum dosage of 1 g/day.

		Cloracef® Suspension	
	Child's Weight	**125 mg/5 ml**	**250 mg/5 ml**
20 mg/kg/day	9 kg	½ tsp t.i.d.	--
	18 kg	1 tsp t.i.d.	½ tsp t.i.d.
40 mg/kg/day	9 kg	1 tsp t.i.d.	½ tsp t.i.d.
	18 kg	--	1 tsp t.i.d.

B.I.D. Treatment Option: For the treatment of otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours.

		Cloracef® Suspension
	Child's Weight	**375 mg/5 ml**
20 mg/kg/day (Pharyngitis)	9 kg	--
	18 kg	½ tsp b.i.d.
40 mg/kg/day (Otitis Media)	9 kg	½ tsp b.i.d.
	18 kg	1 tsp b.i.d.

Cloracef® may be administered in the presence of impaired renal function. Under such a condition, the dosage usually is unchanged.
In the treatment of ß-hemolytic streptococcal infections, a therapeutic dosage of **Cloracef®** should be administered for at least 10 days.

OVERDOSAGE:
- The toxic symptoms following an overdose of cefaclor may include nausea, vomiting, epigastric distress and diarrhea.
- Absorption of the drug from gastrointestinal tract may be decreased by giving activated charcoal, which in many cases is more effective than emesis or gastric lavage. Repeated doses of charcoal over time may accelerate the elimination of the drug that has been absorbed.

PRESENTATIONS:
Cloracef® 250 Capsules: Packs of 16 and 500 capsules. Each capsule contains 250 mg Cefaclor (as cefaclor monohydrate).
Cloracef® 500 Forte Capsules: Packs of 16 and 500 capsules. Each capsule contains 250 mg Cefaclor (as cefaclor monohydrate).
Cloracef® 125 Suspension: Bottles of 75 ml. Each 5 ml (teaspoonful) contains 125 mg Cefaclor (as cefaclor monohydrate).
Cloracef® 250 Forte Suspension: Bottles of 75 ml. Each 5 ml (teaspoonful) contains 250 mg Cefaclor (as cefaclor monohydrate).
Cloracef® 375 Suspension: Bottles of 75 ml. Each 5 ml (teaspoonful) contains 375 mg Cefaclor (as cefaclor monohydrate).

STORAGE CONDITIONS:
Capsules: Protect from light, store in a dry place below 25°C.
Suspension: Keep tightly closed. Protect from light. Store between 15-30°C. After reconstitution store in the refrigerator between 2-8°C. Discard unused portion after 14 days.

This is a medicament.
- *Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.*
- *Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.*
- *The doctor and the pharmacist are experts in medicine, its benefits and its risks.*
- *Do not, by yourself, interrupt the period of treatment prescribed.*
- *Do not repeat the same prescription without consulting your doctor.*

Keep medicament out of reach of children

Manufactured by Dar Al Dawa, Na'ur - Jordan

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10/06