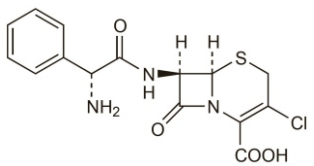
Rx CEFACLOR

XEZTRON®
125 mg/5 mL
Granules for Suspension
Antibacterial
(Cephalosporin)

FORMULATION
Each 5 mL (1 teaspoonful) contains:
CEFACLOR (as monohydrate), USP……125 mg

PHARMACOLOGIC CATEGORY
Cefaclor is a semisynthetic second generation cephalosporin and like other cephalosporins is an inhibitor of bacterial cell wall synthesis. It acylates membrane-bound transpeptidase enzymes thus preventing the cross-linking of peptidoglycan necessary for bacterial cell wall strength and rigidity.

DESCRIPTION
A white to off-white crystalline powder. Slightly soluble in water; practically insoluble in chloroform, in methyl alcohol, and in benzene. pH of a 2.5% suspension in water is between 3.0 and 4.5. Store in airtight containers.



ANTIMICROBIAL ACTION
Cefaclor is bactericidal and has antimicrobial activity similar to that of cefalexin but is reported to be more active against Gram-negative bacteria including *Escherichia coli, Klebsiella pneumoniae, Neisseria gonorrhoeae,* and *Proteus mirabilis*, and especially against *Haemophilus influenzae*. It is active against some beta-lactamase-producing strains of *H. influenzae*. It may be less resistant to staphylococcal penicillinase than cefalexin or cefradine and a marked inoculum effect has been reported *in vitro*.

PHARMACOKINETICS
Cefaclor is well absorbed from the gastrointestinal tract. Oral doses of 250 mg, 500 mg, and 1 g produce peak plasma concentrations of about 7, 13, and 23 micrograms/mL respectively after 0.5 to 1 hour. The presence of food may delay the absorption of cefaclor, but the total amount absorbed is unchanged. A plasma half-life of 0.5 to 1 hour has been reported; it may be slightly prolonged in patients with renal impairment. About 25% is bound to plasma proteins. Cefaclor appears to be widely distributed in the body; it crosses the placenta and low concentrations have been detected in breast milk. It is rapidly excreted by the kidneys; up to 85% of a dose appears unchanged in the urine within 8 hours, the greater part within 2 hours. High concentrations of cefaclor are achieved in the urine within 8 hours of a dose; peak concentrations of 600, 900, and 1900 micrograms/mL have been reported after doses of 0.25, 0.5,and 1 g respectively. Probenecid delays excretion. Some cefaclor is removed by haemodialysis.

INDICATIONS
For the treatment of susceptible infections including upper and lower respiratory-tract infections, skin infections, and urinary-tract infections.

DOSAGE AND MODE OF ADMINISTRATION
Over 5 years old :10 mL or 2 teaspoonfuls three times daily.
1 – 5 years old :5 mL or 1 teaspoonful three times daily.
Under 1 year old :2.5 mL or ½ teaspoon three times daily.
Or as prescribed by a physician.

DIRECTIONS FOR RECONSTITUTION
Shake the bottle to loosen the granules. To make a 60 mL reconstituted suspension, mix thoroughly the contents with 42 mL water and shake well until the granules are evenly suspended.
The reconstituted suspension is stable for 7 days at temperatures not exceeding 30°C and 14 days when refrigerated (2°C- 8°C).

CONTRAINDICATIONS
Previous allergic reactions (anaphylaxis to penicillin, penicillin derivatives, penicillamine or cephalosporins).

PRECAUTIONS
Risk vs. benefit should be carefully considered when following medical problems exist: History of bleeding disorders. Ulcerative colitis, regional enteritis or pseudomembranous colitis.

WARNING
Cefaclor should not be given to patients who are hypersensitive to it or to other cephalosporins.
Cefaclor should be given with caution to patients with renal impairment; dosage reduction may be necessary.
Cefaclor are considered to be unsafe in patients with porphyria.

INTERACTIONS
Anticoagulants- Monitoring of prothrombin time should be considered in patients receiving cefaclor and warfarin after rare reports of increased prothrombin times. It is not known whether this interaction is related to the vitamin K-related hypoprothrombinaemia observed with some cephalosporins, but cefaclor does not contain the side chain usually implicated in this reaction.

ADVERSE DRUG REACTIONS
Cefaclor is generally well tolerated. However among the reported adverse effects mild gastrointestinal reactions (nausea, vomiting, abdominal cramps and diarrhea) are more common. Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. The other side effects are allergic in nature viz, skin rashes, itching, bronchospasm, hypertension, erythema multiforme, Stevens-Johnson Syndrome, Serum sickness like reactions have also been reported with use of Cefaclor. Other side effects are haemolytic anemia, hypoprothrombinemia and thrombophlebitis have been rarely reported.

OVERDOSAGE AND TREATMENT
The toxic symptoms following an overdose of cefaclor may include nausea, vomiting, epigastric distress, and diarrhea. The severity of the epigastric distress and the diarrhea are dose-related. If other symptoms are present, it is probable that they are secondary to an underlying disease state, an allergic reaction, or the effects of other intoxication. gastrointestinal decontamination will not be necessary Unless 5 times the normal dose of cefaclor has been ingested. Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cefaclor.

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

AVAILABILITY
Plastic bottle with measuring cup x 60 mL; (Box of 1's)

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"
Seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER
DRP-075

DATE OF FIRST AUTHORIZATION/RENEWAL
September 11, 2006

DATE OF REVISION
November 2021

Manufactured by:
JM TOLMANN LABORATORIES,INC.
#95 North Zuzuarregui St., Diliman, Q. C.

170 mm

106 mm

FRONT

BACK

INSERT Required size:
105mm x 170mm
Required folding:
2 Folds crosswise (facing the text)