UPDATED PM's of
CEFACLOR monohydrate
(**XEZTRON**) 50mg/mL GFS OD
Prepared by: DBV 08/08/2018
Checked by: HOB 08/08/2018
Approved by: MTA

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

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CEFACLOR
monohydrate

XEZTRON®

50 mg/mL Granules for Suspension
(Oral Drops)
ANTIBACTERIAL

FORMULATION
Each mL (Reconstituted suspension) contains:
CEFACLOR (as monohydrate)……50 mg

DESCRIPTION
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.

CLINICAL PHARMACOLOGY
Cefaclor is well absorbed after oral administration to fasting subjects. Total absorption is the same whether the drug is given with or without food; however, when it is taken with food, the peak concentration achieved is 50% to 75% of that observed when the drug is administered to fasting subjects and generally appears from three fourths to 1 hour later. Following administration of 250 mg, 500 mg, and 1 g doses to fasting subjects, average peak serum levels of approximately 7, 13, and 23 µg/mL respectively were obtained within 30 to 60 minutes. Approximately 60% to 85% of the drug is excreted unchanged in the urine within 8 hours, the greater portion being excreted within the first 2 hours. During this period, peak urine concentrations following the 250 mg, 500 mg and 1 g doses were approximately 600, 900, 1,900 µ/mL, respectively. The serum half-life in normal subjects is 0.6 to 0.9 hour. In patients with reduced renal function, the serum half-life of cefaclor is slightly prolonged. In those with complete absence of renal function, the plasma half-life of the intact molecule is 2.3 to 2.8 hours. Excretion pathways in patients with markedly impaired renal function have not been determined. Hemodialysis shortens the half-life by 25% to 30%.

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 kidney; up to 85% of a dose appears unchanged in the urine within 8 hours, the greater part within 2 hours. High concentration 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 ADMINISTRATION
Children: Over 1 month old: 20 mg/kg body weight in three divided doses increased if necessary to 40 mg/kgdaily doses of but not exceeding a total daily dose of 1 g.
Under 1 year old : 62.5 mg three times daily.
Or as prescribed by a physician.

DIRECTIONS FOR RECONSTITUTION
For 50 mg/mL Granules for Suspension (Oral Drops)
To make a 10 mL reconstituted suspensions, add 7 mL water and shake well until the contents 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).

PRECAUTION
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.

PREGNANCY AND LACTATION
Pregnancy: (Category B) Reproduction studies using cefaclor performed in mice, rats, and ferrets at doses up to 3 to 5 times the maximum human dose (1,500 mg/day) based on mg/m^2 have revealed no harm to the fetus. No adequate and well controlled studies have been done in pregnant women. Use in pregnancy only if clearly needed.

Lactation: Small amounts of cefaclor (0.16-0.21 mcg/mL) have been detected in human milk after administration of single 500 mg doses. Use with caution in breastfeeding women.

DRUG INTERACTION
The renal excretion of cefaclor, and many other cephalosporins is delayed by probenecid.

ADVERSE 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
Overdosage of cefaclor may cause nausea, vomiting epigastric distress, and diarrhea; the severity of epigastric distress and diarrhea are dose related. If other symptoms are present, they probably are secondary to an underlying disease state, an allergic reaction, or the effects of other intoxication. Gastrointestinal decontamination is not necessary unless 5 times the normal dose of cefaclor has been ingested. The benefits of forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion in treating cefaclor overdosage have not been established.

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

AVAILABILITY
Granules for Suspension (Oral Drops)
Bottle of 30 mL (10 mL net volume) in individual boxes with individual dropper.

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

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph"

REGISTRATION NUMBER
DRP-2558

DATE OF REVISION
SEPTEMBER 2016

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

NEW REVISED PACKAGING