CLOROCEF

CEFACLORE MONOHYDRATE BP

Compositions:
Clorocef 250 Capsule: Each capsule contains Cefaclor 250 mg as Cefaclor Monohydrate BP. Clorocef 500 Capsule: Each capsule contains Cefaclor 500 mg as Cefaclor Monohydrate BP. Clorocef 100 ml Suspension: After reconstitution, each 5 ml suspension contains Cefaclor 125 mg as Cefaclor Monohydrate BP. Clorocef 15 ml Paediatric Drops: After reconstitution, each 1.25 ml paed. drops Contains Cefaclor 125 mg as Cefaclor Monohydrate BP.

Pharmacology:
Clorocef (Cefaclor) is a second generation broad spectrum semisynthetic cephalosporin antibiotic. It has stability against ß-lactamase. Cefaclor is active against the following organisms in vitro: Aerofobes Gram-positive: Staphylococci including coagulase-positive, coagulase-negative and penicillinase-producing strains, Streptococcus pneumoniae, Streptococcus pyogenes group A (ß-hemolytic streptococci) Aerobes Gram-negative: Escherichia coli, Haemophilus influenzae, Klebsiella spp. Proteus mirabilis excluding (ß-lactamase negative ampicillin-resistant strains).

Dosage And Administration:
Clorocef is administered orally. Adults: The usual adult dose is 250 mg every eight hours. For severe infections or those caused by less susceptible organisms, doses may be doubled. The elderly dose is as for adults. Children: The usual recommended daily dose for children is 20 mg/kg/day in divided doses every 8 hours. In more severe infections, otitis media and infections caused by less susceptible organisms, 40 mg/kg/day in divided doses are recommended with a maximum dosage of 1g/day. Safety and efficacy have not been established for use in infants aged less than one month. Another recommendation is as follows: For Age < 1 year 9 Kg: 2.5 ml t.i.d Clorocef suspension (125 mg/ 5 ml) & 0.625 ml t.i.d Clorocef pediatric drops (125 mg/ 1.25 ml) for Age:1-5 years (9 kg- 18 kg) 5.0 ml t.i.d Clorocef suspension (125 mg/ 5 ml) & 1.25 ml t.i.d Clorocef pediatric drops (125 mg/ 1.25 ml) Over 5 years 10 ml t.i.d Clorocef suspension (125 mg/ 5 ml) In the treatment of ß-haemolytic streptococcal infections, therapy should be continued for at least 10 days. 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. Patients undergoing haemodialysis: Haemodialysis shortens serum half-life by 25-30%. In patients undergoing regular haemodialysis, a loading dose of 250 mg - 1 g administered prior to dialysis and a therapeutic dose of 250-500 mg every six to eight hours maintained during interdialytic periods is recommended.

Contraindications:
Clorocef is contraindicated in patients hypersensitive to Cephalosporins. Cefaclor should be administered with caution in the presence of markedly impaired renal function. Modification of usual dosage usually is not necessary in patients with moderate or severe renal impairment. Prolonged use of Cefaclor may result in the overgrowth of non-susceptible organisms. If super infection occurs during therapy, appropriate measures should be taken. If an allergic reaction to Cefaclor occurs, the drug should be discontinued and the patient should be treated with appropriate agents.

Warning And Precaution:
In penicillin-sensitive patients, cephalosporin antibiotics should be administered cautiously. Past history of a severe allergic reaction to penicillin/cephalosporin is a contraindication to the use of Clorocef. If an allergic reaction occurs, Clorocef should be discontinued and the

appropriate therapy instituted

Side Effects:
Gastro-intestinal: Diarrhoea, nausea and vomiting have been reported. Hypersensitivity: Allergic reactions such as eruptions, pruritis and urticaria have been observed. These reactions usually subside upon discontinuation of therapy. Serum sickness like reaction have been reported. Haematological: Eosinophilia, thrombocytopenia, transient lymphocytosis and leucopenia may occur rarely. Hepatic: Transient hepatitis and cholestatic jaundice, slight elevation in AST, ALT or alkaline phosphate values have been reported rarely. Renal: Reversible interstitial nephritis has occurred rarely, also slight elevations in blood urea or serum creatinine or abnormal urinalysis. Central Nervous System: Reversible hyperactivity, nervousness, confusion, hypertonia, dizziness, hallucinations and somnolence have been reported rarely.

Use in Pregnancy and Lactation:
Animal studies have shown no evidence of impaired fertility or teratogenicity. However, caution is recommended in the use of the drug in early pregnancy. Lactation: Small amounts of Cefaclor have been detected in breast milk following administration of single 500 mg doses. As the effect on nursing infants is not known, caution should be exercised when Cefaclor is administered to a nursing mother.

Drug Interaction:
The nephrotoxicity of amino glycoside antibiotics such as gentamicin and tobramicin may be enhanced by any Cephalosporin. Therefore, one should be cautious in concomitant use of these categories of drugs.

Overdosage:
Symptoms of nausea, vomiting, epigastric distress and diarrhoea would be anticipated. Treatment: Unless 5 times the normal total daily dose has been ingested, gastrointestinal decontamination will not be necessary. General management may consist of supportive therapy.

Storage:
Store at room temperature and protect from light. After reconstitution the suspension can be used within 7 days if kept at room temperature and within 14 days if kept in refrigerator (2-8°C). Always keep the bottle tightly closed.

Packing:
Clorocef 250 Capsule: Each box contains 12 capsules in Alu-Alu blister pack. Clorocef 500 Capsule: Each box contains 12 capsules in Alu-Alu blister pack. Clorocef 100 ml Suspension: Each bottle contains dry powder to reconstitute 100 ml suspension with a spoon. Clorocef 15 ml Paediatric Drops: Each bottle contains dry powder to reconstitute 15 ml drops with a spoon and a paediatric dropper.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.