Loracef ®

COMPOSITION
Loracef ® 500 capsule : Each capsule contains Cefaclor 500 mg as Cefaclor Monohydrate USP.
Loracef ® suspension : Each 5 ml reconstituted suspension contains Cefaclor 125 mg as Cefaclor Monohydrate USP.
Loracef ® paediatric drops: Each 1.25 ml reconstituted suspension
contains Cefaclor 125 mg as Cefaclor monohydrate USP.
Loracef ® ER: Each extended release tablet contains Cefaclor 375 mg as Cefaclor Monohydrate USP.

PHARMACOLOGY
Cefaclor is a second generation cephalosporin antibiotic which has
stability against b-lactamase inactivation and possesses a broad
spectrum of activity.
Cefaclor is active against the following organisms in vitro:
Alpha and beta haemolytic Streptococci, Staphylococci; including
coagulase-positive, coagulase-negative and penicillinase-producing strains, Streptococcus pneumoniae, Streptococcus pyogenes (Group A b-haemolytic Streptococci),
Branhamella catarrhalis, Escherichia coli, Proteus mirabilis, Klebsiella species Haemophilus influenzae, including ampicillin-resistant strains.
Cefaclor is generally effective in the eradication of Streptococci from the nasopharynx.

INDICATION
Loracef ® (Cefaclor) is indicated for the treatment of the following
infections due to susceptible micro-organisms :
Respiratory tract infections including pneumonia, bronchitis,
exacerbation of chronic bronchitis, pharyngitis, tonsillitis and as part of the management of sinusitis.
Otitis media
Skin and soft tissue infections
Urinary tract infections including pyelonephritis and cystitis. It is
effective in both acute and chronic urinary tract infections.

DOSAGE AND ADMINISTRATION
Loracef ® (Cefaclor) is administered orally
Adult:
Usual dose is 250 mg every 8 hourly, or 500 mg every 8 hourly in case of sever infections. Maximum 4 g daily
Children:
Over 1 month, 20 mg/kg daily in 3 divided doses, doubled for severe infections. Maximum 1 gm daily or as follows:

Suspension:

1 month to 1 year	2.5 ml every 8 hourly
1 to 5 years	5.0 ml every 8 hourly
Over 5 years	10.0 ml every 8 hourly

Drops:

1 month to 1 year	0.625 ml every 8 hourly

Loracef ® ER:
The recommended dosage for pharyngitis and tonsillitis, skin and skin structure infections, lower urinary tract infections and bronchitis is 375 mg twice daily. For pneumonia and sinusitis the recommended dosage is 750 mg twice daily.
Loracef ® ER tablets should not be cut, crushed or chewed.

DIRECTION FOR RECONSTITUTION
Dry suspension:
First shake the bottle to loosen the powder. To prepare 100 ml
suspension add 60 ml boiled and cooled water and shake well untill the powder is completely mixed with water.
Paediatric drops:
First shake the bottle to loosen the powder. To prepare 15 ml
suspension add 10 ml boiled and cooled water and shake well untill the powder is completely mixed with water.

CONTRAINDICATION AND PRECAUTION
Cefaclor 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.
If an allergic reaction to Cefaclor occurs, the drug should be
discontinued and the patient should be treated with appropriate agents.

SIDE EFFECT
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 up on discontinuation of therapy. Serum sickness like reactions 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.

DRUG INTERACTION
The nephrotoxicity of aminoglycoside 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.

USE IN PREGNANCY AND LACTATION
Pregnancy: 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 women.

STORAGE CONDITION
Store in normal temperature protected from light and moisture.
After reconstitution the suspension & the drops can be used within 7 days if kept at normal temperature and within 14 days if kept in
refrigerator (20- 80 C). Always keep the bottle tightly closed.

HOW SUPPLIED
Loracef ® 500 capsule: Box containing 1x6's capsules in Alu-Alu blister pack.
Loracef ® suspension: Bottle containing dry powder to make 100 ml suspension and a measuring cup.
Loracef ® paediatric drops: Bottle containing dry powder to make 15 ml paediatric drops, a dropper and a spoon.
Loracef ® ER: Box containing 2x5's extended release tablet in Alu-Alu blister pack