Loracef®
Cefaclor

COMPOSITION
Loracef® Powder for Suspension: Each 5 ml reconstituted suspension contains Cefaclor 125 mg as Cefaclor Monohydrate USP.
Loracef® Paediatric Drops: Each 1.25 ml reconstituted drops contains Cefaclor 125 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.

INDICATION
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
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 1 gm/day. Safety and efficacy have not been established for use in infants aged less than one month.
Loracef® Suspension
< 1 year (9 kg) 2.5 ml t.i.d.
1-5 years (9-18 kg) 5.0 ml t.i.d.
Over 5 years 10.0 ml t.i.d.
In the treatment of beta-haemolytic streptococcal infections, therapy should be continued for at least 10 days.
For the treatment of otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours.

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.
Prolonged use of Cefaclor may result in the overgrowth of non-susceptible organisms. If super infection occurs during therapy, appropriate measures should be taken.

SIDE EFFECT
Diarrhoea, nausea and vomiting have been reported. Allergic reactions such as eruptions, pruritis and urticaria have been observed. These reactions usually subside up on discontinuation of therapy. Eosinophilia, thrombocytopenia, transient lymphocytosis and leucopenia may occur rarely. Transient hepatitis and cholestatic jaundice, slight elevation in AST, ALT or alkaline phosphate values have been reported rarely. Reversible interstitial nephritis has occurred rarely, also slight elevations in blood urea or serum creatinine or abnormal urinalysis. 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: Caution is recommended in the use of the drug in early pregnancy.
Lactation: As the effect on nursing infants is not known, caution should be exercised when Cefaclor is administered to a nursing mother.

OVER DOSAGE
Symptoms of nausea, vomiting, epigastric distress and diarrhoea would be anticipated. 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 CONDITION
Capsule: Store below 30^0 C, protect from light and moisture.
Suspension & Paediatric Drops: Store below 25^0 C, protect from light and moisture. After reconstitution the suspension & paediatric drops can be used within 7 days if kept at room temperature and within 14 days if kept in refrigerator (2^0- 8^0 C).

HOW SUPPLIED
Loracef® Powder for Suspension: Bottle containing dry powder to reconstitute 100 ml suspension and a measuring cup.
Loracef® Paediatric Drops: Bottle containing dry powder to reconstitute 15 ml paediatric drops. It also contains a spoon and a dropper.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Bangladesh

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