Lebac™

Cephradine

COMPOSITION

Lebac™ 250 capsule: Each capsule contains Cephradine USP 250 mg. **Lebac**™ 500 capsule: Each capsule contains Cephradine USP 500 mg. **Lebac**™ Powder for Suspension: After reconstitution each 5 ml suspension contains Cephradine USP 125 mg. **Lebac**™ Forte Powder for Suspension: After reconstitution each 5 ml suspension contains Cephradine USP 250 mg. **Lebac**™ 500 mg IM/IV injection: Each vial contains Cephradine USP 500 mg. **Lebac**™ 1 gm IM/IV injection: Each vial contains Cephradine USP 1 gm. **Lebac**™ Paediatric Drops: After reconstitution each 1.25 ml drops contains Cephradine USP 125 mg.

PHARMACOLOGY

Lebac™ (Cephradine) is a cephalosporin antibiotic with broad spectrum bactericidal activity against both gram-positive and gram-negative bacteria. **Lebac**™ interferes with the synthesis of bacterial cell wall by inhibiting transpeptidase enzyme. As a result the bacterial cell wall is weakened, the cell swells and then ruptures.

INDICATION

Lebac™ (Cephradine) is used in the treatment of infections caused by sensitive organisms. Upper respiratory tract infections: Pharyngitis, sinusitis, otitis media, tonsilitis, laryngotracheo-bronchitis; Lower respiratory tract infections: Acute and chronic bronchitis, lobar and bronchopneumonia. Urinary tract infections: Cystitis, urethritis, pyelonephritis; Skin and soft tissue infections: Abscess, cellulitis, furunculosis, impetigo; Gastrointestinal tract infections: Bacillary dysentery, enteritis, peritonitis. Bone and joint infection; Surgical prophylaxis: It is also used in perioperative prophylactic administration (pre-operatively, intra-operatively and post-operatively). In cesarean section, intra-operative (after clamping the umbilical cord) and post-operative use may reduce the incidence of certain post-operative infections.

DOSAGE AND ADMINISTRATION

The dosage may be given without regard to meals.

Adult:

Oral: The usual dose is 1-2 gm daily in 2 to 4 divided doses. In severe and prolonged infection, the dose can be increased up to 4 gm daily which should be taken in equally divided doses. Injection: The usual dose is 2-4 gm daily which should be given intramuscularly or intravenously in 3-4 divided doses. Special dose in the following infections : Skin and skin structures and respiratory tract infection: Usual dose is 250 mg every 6 hours or 500 mg every 12 hours. Lobar pneumonia: 500 mg every 6 hours or 1 gm every 12 hours. Urinary tract infection: Usual dose is 500 mg every 12 hours. Gastro-intestinal tract infection: 500 mg three to four times daily.

Children:

Oral: The usual total dose is 25 to 50 mg/kg/day given in 2 to 4 equally divided doses. Injection: 50 to 100 mg/kg/day in 4 equally divided doses. The usual total dose may be increased up to 200-300 mg/kg/day. Perioperative prophylaxis: Recommended dose is 1-2 gm by intramuscular or intravenous route; subsequent parenteral or oral doses are given as appropriate. Therapy should be continued for a minimum of 48-72 hrs. after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

Dosage in renal impairment: In patients with impaired renal function, doses and frequency of administration of cephradine must be modified according to the degree of impairment, severity of infection, susceptibility of the causative organism and serum concentration of the drug. For adults, a loading dose of 750 mg should be given subsequently followed by 500 mg with the mentioned time interval.

Creatinine clearance (ml/min)	Time interval (hrs)
> 20	6-12
15-19	12-24
10-14	24-40
5-9	40-50
<5	50-70

For children, dosage schedule may need to be adjusted.

Reconstitution & administration

Lebac™ *Powder for Suspension:* For the suspension, shake the bottle well before adding water. Then add 60 ml of boiled and cooled water (with the help of the provided cup) to the bottle. Then continue shaking the bottle gently until the powder is mixed properly. Shake the bottle well before each use. **Lebac**™ *Forte Powder for Suspension:* For the suspension, shake the bottle well before adding water. Then add 60 ml of boiled and cooled water (with the help of the provided cup) to the bottle. Then continue shaking the bottle gently until the powder is mixed properly. Shake the bottle well before each use. **Lebac**™ *Paediatric Drops:* Shake the bottle well before adding water. Then add 10 ml (or with the help of provided spoon) of boiled and cooled water. Then continuously shake the bottle well until the powder is mixed properly. Shake the bottle well before each use. **Lebac**™ *500 mg IM/IV Injection:* Intramuscular: Add 2.0 ml of water for injection BP to 500 mg vial and shake. Intravenous: Add 5.0 ml of water for injection BP to 500 mg vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

Lebac™ *1 gm IM/IV Injection:* Intramuscular: Add 4.0 ml of water for injection BP to 1 gm vial and shake. Intravenous: Add 10.0 ml of water for injection BP to 1 gm vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

SIDE EFFECT

Side effects include nausea, vomiting, diarrhoea and abdominal discomfort. Allergic reactions including skin rashes, urticaria, eosinophilia, angioedema and anaphylaxis may occur and elevation of hepatic enzyme values have been noted. Neutropenia has been reported. Super-infection with resistant microorganisms, particularly candida, may follow the treatment. There is also a possibility of development of pseudomembranous colitis. Transient pain may be experienced at the injection site. Thrombophlebitis has been reported following intravenous administrations.

PRECAUTION

Cephradine should be used with caution in those patients who are known hypersensitive to penicillins.

USE IN PREGNANCY AND LACTATION

Although there have been no reports of adverse effect on the fetus, safety of use during pregnancy has not been definitely established. The drug should be used during pregnancy only when clearly indicated. Cephalosporins are distributed into breast milk and the drug should be used with caution in nursing mother.

CONTRAINDICATION

It should not be used in patients hypersensitive to any cephalosporin antibiotic.

STORAGE CONDITION

Cephradine capsule should be kept below 30^0 C. Cephradine dry powder for suspension should be kept below 25^0 C & powder vial for injection should be kept below 25^0 C. The reconstituted suspension, forte suspension and paediatric drops should be used within 7 days of preparation if kept at room temperature or within 14 days if kept in a refrigerator. The Cephradine solution should be protected from bright or direct sunlight. All strengths of reconstituted products should be used immediately. The reconstituted Cephradine injection solution should be used within 2 hours of preparation if kept at room temperature or within 12 hours when refrigerated at 2^0-8^0 C.

HOW SUPPLIED

Lebac™ 250 Capsule: Box containing 18 capsules in blister pack.

Lebac™ 500 Capsule: Box containing 30 capsules in blister pack.

Lebac™ Powder for Suspension: Bottle containing dry powder to reconstitute 100 ml suspension with a measuring cup.

Lebac™ Forte Powder for Suspension: Bottle containing dry powder to reconstitute 100 ml suspension with a measuring cup.

Lebac™ 500 mg IM/IV Injection: Pack of 1 vial accompanied by 1 ampoule of 5 ml Water for injection BP for IM or IV injection. It also contains a complementary pouch comprised of disposable syringe (5 ml), baby needle, alcohol pad and first aid bandage.

Lebac™ 1 gm IM/IV Injection: Pack of 1 vial accompanied by 1 ampoule of 10 ml Water for injection BP for IM or IV injection. It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid bandage.

Lebac™ Paediatric Drops: Bottle containing dry powder to reconstitute 15 ml drops with a 5 ml spoon & a dropper.

Manufactured by:

SQUARE
CEPHALOSPORINS LTD.
BANGLADESH

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