



**Lebac<sup>®</sup>**

Cephadrine

**First generation Cephalosporin**

### COMPOSITION

- Lebac<sup>®</sup> 250 capsule : Each capsule contains Cephadrine BP 250 mg.  
Lebac<sup>®</sup> 500 capsule : Each capsule contains Cephadrine BP 500 mg.  
Lebac<sup>®</sup> Dry syrup : After reconstitution each 5 ml syrup contains Cephadrine BP 125 mg.  
Lebac<sup>®</sup> Forte syrup : After reconstitution each 5 ml syrup contains Cephadrine BP 250 mg.  
Lebac<sup>®</sup> 500 injection : Each vial contains Cephadrine BP 500 mg.  
Lebac<sup>®</sup> 1gm injection : Each vial contains Cephadrine USP 1 gm.  
Lebac<sup>®</sup> Paediatric drops : After reconstitution each 1.25 ml drops contains Cephadrine BP 125 mg.

### INDICATION

Lebac<sup>®</sup> (Cephadrine) is used in the treatment of infections caused by sensitive organisms.

Upper respiratory tract infections: Pharyngitis, sinusitis, otitis media, tonsillitis, 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.

<b>Creatinine clearance (ml/min)</b>	<b>Time interval (hrs)</b>
> 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 and Administration:**

Lebac<sup>®</sup> Dry Syrup:

For the syrup, shake the bottle well before adding water. Then add 60 ml of boiled and cool water (with the help of the provided cup) to the bottle. Then continue shaking the bottle gently until the powder is dissolved properly. Shake the bottle well before each use.

Lebac<sup>®</sup> Forte Syrup:

For the syrup, shake the bottle well before adding water. Then add 60 ml of boiled and cool water (with the help of the provided cup) to the bottle. Then continue shaking the bottle gently until the powder is dissolved properly.

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Shake the bottle well before each use.

Lebac<sup>®</sup> 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 dissolved properly. Shake the bottle well before each use.

Lebac<sup>®</sup> 500 mg Injection:

*Intramuscular* : Add 2.0 ml of water for injection to 500 mg vial and shake.

*Intravenous* : Add 5.0 ml of water for injection to 500 mg vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

Lebac<sup>®</sup> 1 gm Injection:

*Intramuscular* : Add 4.0 ml of water for injection to 1gm vial and shake.

*Intravenous* : Add 10.0 ml of water for injection to 1gm vial and shake. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

### **CONTRAINDICATION AND PRECAUTION**

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

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

### **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.

### **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.

**STORAGE CONDITION**

Cephadrine capsule, dry powder for syrup and powder vial for injection should be kept in a cool and dry place, protected from light. The reconstituted syrup 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. The reconstituted Cephadrine injection solution should be used within 2 hours of preparation if kept at room temperature or within 12 hours if kept under 5° C.

**HOW SUPPLIED**

- Lebac® 250 capsule : Box containing 3 x 6 Lebac® 250 capsules in Alu-Alu blister pack.
- Lebac® 500 Capsule : Box containing 5X6 Lebac® 500 capsules in Alu-Alu blister pack.
- Lebac® Dry Syrup : Bottle containing Lebac® dry powder to reconstitute 100 ml syrup.
- Lebac® Forte Syrup : Bottle containing Lebac® dry powder to reconstitute 100 ml syrup.
- Lebac® 500 mg Injection : Box containing 5 blister packs, each blister contains one Lebac® 500 vial and one ampoule of 5 ml water for injection.
- Lebac® 1 mg Injection : Box containing 1 blister pack. Each blister pack contains one Lebac® 1 gm vial and one ampoule of 10 ml water for injection & a 10 ml disposable syringe.
- Lebac® Paediatric Drops : Bottle containing Lebac® dry powder to reconstitute 15 ml drops with one spoon & a dropper.

