

Avlosef[®]

Cephadrine

Presentation

Avlosef[®] 250mg Capsules: Each capsule contains Cephadrine USP 250mg.

Avlosef[®] 500mg Capsules: Each capsule contains Cephadrine USP 500mg.

Avlosef[®] Powder for Suspension 125mg/5ml: Each 5ml contains Cephadrine USP 125mg.

Avlosef[®] Powder for Suspension 250mg/5ml: Each 5ml contains Cephadrine USP 250mg.

Avlosef[®] Paediatric Drops: Each 1.25ml contains Cephadrine USP 125mg. A dropper to measure the 1.25ml dose is provided.

Avlosef[®] 500mg Injection: Each vial contains 500mg Cephadrine USP as powder of Cephadrine and L-arginine.

Avlosef[®] 1g Injection: Each vial contains 1g Cephadrine USP as powder of Cephadrine and L-arginine.

Uses

Avlosef[®] a broad-spectrum bactericidal antibiotic, exhibits activity against a wide range of Gram-positive and Gram-negative bacteria. It is also highly active against most strains of penicillinase producing Staphylococci.

Avlosef[®] is indicated in the treatment of following infections:

Respiratory tract infections: Pharyngitis, sinusitis, otitis media, tonsillitis, laryngo-tracheobronchitis, acute and chronic bronchitis, lobar and bronchopneumonia.

Urinary tract infections: Cystitis, urethritis, pyelonephritis, prostatitis, epididymitis.

Skin and soft tissue infections: Abscess, cellulitis, furunculosis, impetigo.

Gastro-intestinal tract infections: Bacillary dysentery, enteritis, peritonitis.

Avlosef[®] is also in the prophylaxis of infections during surgical procedures.

Dosage and administration

Oral dosage

Avlosef[®] may be given without regard to meal.

Adults:

Urinary tract infections: 500mg four times or 1g twice daily. In case of prostatitis or epididymitis, prolonged intensive therapy is needed.

Respiratory tract, skin and soft tissue infections: 250mg or 500mg four times daily or 500mg or 1g twice daily.

Gastro-intestinal tract infections: 500mg three or four times daily.

Children: 25 to 50mg/kg/day, in two or four equally divided doses.

Otitis Media: 75 to 100mg/kg/day, in two or four divided doses.

In severe and chronic infections, larger doses may be required, upto a maximum of 4g daily in divided doses.

Parenteral dosage

Adults:

Intramuscular or intravenous: 500mg or 1g every 6 hours, upto 8g daily in severe infections.

Perioperative prophylaxis: In surgery: i.m or i.v 1g one half to one and one half hours prior to the start of surgery and 1g every 6 hours upto 24 hours.

In cesarean section: 1g i.v as soon as the umbilical cord is clamped and 1g i.m or i.v 6 and 12 hours after the first dose.

Children: 1 year of age and above/over; i.m or i.v 12.5 to 25mg/kg body weight every 6 hours.

Upto 300mg/kg body weight daily has been in severely ill infants and children without apparent adverse effects.

Premature infants and infants upto 1 year of age: dosage has not been established.

Administration

Intramuscular: 500mg dissolve in 2ml water for injection BP and 1g dissolve in 4ml water for injection BP.

Intravenous: 500mg dissolve in 5ml water for injection BP and 1g dissolve in 10ml water for injection BP, 5% dextrose injection or Sodium chloride injection.

The resulting solution should be administered over a 3-5 minutes period.

Intermittent i.v use : 1g dissolve in 10ml of suitable diluent.

Treatment should be continued for a minimum of 48 to 72 hours after the patient becomes asymptomatic. A minimum of 10 day's treatment recommended for infection caused by haemolytic strains of Streptococci. Persistent infection may require treatment for several weeks. In severe and chronic infection, larger doses may be required upto 1g 4 times a day.

Renal impairment dosage: Adult: Based on the creatinine clearance a loading dose of 750mg of Avlocef® may be given followed by maintenance dose of 500mg at the time interval listed below :

Creatinine clearance ml/min/1.73m ²	Time interval
>20ml/min	6-12 hours
15-19ml/min	12-24 hours
10-14ml/min	24-40 hours
5-9ml/min	40-50 hours
<5ml/min	50-70 hours

Further modification of the dosage schedule may be necessary in children.

Contra-indications, warnings, etc.

Contra-indications: Known hypersensitivity to cephalosporin.

Precautions: Known hypersensitivity to penicillin.

Use in pregnancy: Animal studies have not shown any teratogenicity during pregnancy. So Avlocef® can be given during pregnancy when antibiotic therapy is indicated.

It is excreted in breast milk and should be used with caution in lactating mothers.

Side-effects

Rarely, Cephadrine may induce a hypersensitivity reaction and gastro-intestinal disturbance which include nausea, vomiting, diarrhoea, glossitis, heartburn, dizziness, tightness in the chest, vaginitis, candidal overgrowth, urticaria, skin rashes, joint pains, oedema, mild transient eosinophilia; leucopenia and neutropenia, positive direct Coombs test and pseudomembranous colitis have been reported.

Pharmaceutical precautions

Avlocef® DS, Avlocef® powder for suspension and Avlocef® paediatric drops should be freshly prepared.

Prepared suspension is to be consumed within 7 days of preparation if kept in room temperature or within 14 days if kept in a refrigerator.

Avlocef® solution for injection should be used immediately after preparation.

Stability: Reconstituted i.m or i.v solution retain their potency for 2 hours at room temperature or 24 hours if refrigerated at 5°C and intravenous infusion 10 hours at room temperature or 48 hours if refrigerated at 5°C.

Incompatibilities: Cephradine USP for injection contains sodium carbonate and therefore is not compatible with lactate Ringers injection, Ringers injection Dextrose, and lactated Ringers injections/calcium containing solutions. Extemporaneous admixture of Cephradine injection with other antibiotics are not recommended. To avoid the substantial mutual inactivation aminoglycoside a cephradine injection should be administered in separate sites.

Storage

Store in a cool and dry place.

Package quantities

Avlosef® 250mg Capsules: Carton of 32 capsules in strips.

Avlosef® 500mg Capsules: Carton of 32 capsules in strips.

Avlosef® Powder for Suspension 125mg/5ml: Bottle of 100ml.

Avlosef® DS Powder for Suspension 250mg/5ml: Bottle of 100ml

Avlosef® Paediatric Drops: Bottle of 15ml.

Avlosef® 500mg Injection: Carton of 1 vial of 500mg and 1 ampoule 5ml water for injection BP

Avlosef® 1g Injection: Carton of 1 vial of 1g and 1 ampoule of 10ml water for injection BP

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