

Aciphin®

Ceftriaxone Sodium

Description

Aciphin® is a bactericidal, long-acting, broad spectrum, parenteral cephalosporin preparation, active against a wide range of gram positive and gram negative susceptible microorganisms. It is also active against the organisms resistant to other antibiotics, including penicillins, other cephalosporins and aminoglycosides.

Indications

Aciphin® is indicated for the following infections caused by sensitive bacteria:

▪ Lower respiratory tract infections:

Etiology- *Streptococcus pneumoniae*, other *Streptococcus species* (excluding enterococci), *Staphylococcus aureus*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella spp.* including *K. pneumoniae*, *Escherichia coli*, *Proteus mirabilis*, *E. aerogenes*, *S. marcescens*.

▪ Urinary tract infections (complicated and uncomplicated):

Etiology- *E. coli*, *P. mirabilis*, *P. vulgaris*, *M. morganni* and *Klebsiella pneumoniae*.

▪ Uncomplicated gonorrhoeae, i.e. cervical, Urethral and rectal:

Etiology- *Neisseria gonorrhoeae*, both penicillinase and non penicillinase producing strains.

▪ Pelvic inflammatory disease: Etiology- *Neisseria gonorrhoeae*.

▪ Septicaemia: Etiology- *S. aureus*, *Strep. pneumoniae*, *E. coli*, *H. influenzae*, *K. pneumoniae*.

▪ Bone and joint infections:

Etiology- *S. aureus*, *S. pneumoniae*, *Streptococci* (excluding enterococci), *E. coli*, *P. mirabilis*, *K. pneumoniae* and *Enterobacter species*.

Intra-abdominal infections: Etiology- *E. coli*, *K. pneumoniae*.

Meningitis:

Etiology- *H. influenzae*, *N. meningitidis*, *Strep. pneumoniae*, *Staph. epidermidis*, *E. coli* and other susceptible Enterobacteriaceae.

Surgical prophylaxis:

Contaminated or potentially contaminated surgery, e.g. vaginal or abdominal hysterectomy, artery bypass surgery, patients for whom infection at the operative site would present serious risk (infections in cancer patients, neutropenic and immunocompromised patients). Ceftriaxone may be given empirically early once daily alone or in combination with other antibiotics for the treatment of a febrile neutropenic patient with a wide variety of commonly encountered oncohematologic diseases.

Miscellaneous infections:

Ceftriaxone has been shown to be effective in treating Streptococcal and Haemophilus endocarditis and is equally effective in typhoid fever using only a 3 days course, compared to Chloramphenicol in standard dosages over 14 days.

Dosage and administration

Aciphin® should be given by deep intramuscular injection, or by intravenous injection over at least 2-4 minutes, or by intravenous infusion. Generally, Aciphin® should be taken once or equally divided twice a day for 4-14 days. Aciphin® therapy should be continued for at least 2-3 days after the signs and symptoms of infection have disappeared.

Adults and children over 12 years: The usual dosage is 1-2 g of Aciphin® once daily (every 24 hours); 2-4 g daily in severe infections; intramuscular doses over 1 g divided between more than one site; single intravenous doses above 1 g by intravenous infusion only.

Children up to 12 years, infants and neonates: The following dosage schedules are recommended for once daily administration:

- Infants and children (15 days to 12 years): by deep intramuscular injection, or by intravenous injection over 2-4 minutes, or by intravenous infusion, 20-50 mg/kg once daily; up to 80 mg/kg once daily in severe infections; doses of 50 mg/kg and over by intravenous infusion over at least 30 minutes.
- Neonates (up to 14 days): by intravenous infusion over 60 minutes, 20-50 mg/kg bodyweight once daily. The daily dose should not exceed 50 mg/kg.

For children with bodyweights of 50 kg or more: the usual adult dosage should be used.

Special dosage instructions

Endocarditis: caused by *Haemophilus*, *Actinobacillus*, *Cardiobacterium*, *Eikenella*, and *Kingella* species, by intravenous infusion, 2-4 g daily.

Uncomplicated gonorrhoea: by deep intramuscular injection, 250 mg as a single dose.

Surgical prophylaxis: by deep intramuscular injection or by intravenous injection over at least 2-4 minutes, 1 g at induction; colorectal surgery, by deep intramuscular injection or by intravenous infusion, 2 g at induction; intramuscular doses over 1 g divided between more than one site.

Meningitis: In bacterial meningitis in infants and children, treatment begins with doses of 100 mg/kg (up to a maximum of 4 g) once daily.

Impaired renal and hepatic function: In patient with impaired renal or hepatic function, there is no need to reduce the dose of Aciphin®. Only in case of preterminal renal failure (Creatinine Clearance < 10 ml/min), the daily dose must not exceed 2g. In patient with liver damage, dose reduction is not required if renal function is intact.

Elderly patients: The dosages recommended for adults require no modification in geriatric patients.

Combination therapy: Simultaneous administration of Aciphin® with diuretics or aminoglycosides in human subject have shown no impairment of renal functions or increased nephrotoxicity.

Reconstitution and preparation for injection

The use of freshly prepared solution is recommended. The reconstituted solution maintain their physical and chemical stability at least 6 hrs at room temperature and 24 hrs at 5°C.

Intramuscular injection: 250mg or 500mg of Aciphin® should be dissolved in 2ml of Xylone, 1% injection (Lidocaine Hydrochloride USP 1%) and 1g in 3.5 ml of Xylone, 1% injection (Lidocaine Hydrochloride USP 1%) solution provided in the accompanying solvent ampoule and administered by deep Intragluteal injection. Dosage greater than 1g should be divided and injected at more than one site.

For intramuscular administration, use of Xylone, 1% injection (Lidocaine Hydrochloride USP 1%) is must to avoid the pain.

Aciphin® in Xylone, 1% injection (Lidocaine Hydrochloride USP 1%) should not be administrated intravenously.

Intravenous injection: 250mg or 500mg of Aciphin® should be dissolved in 5ml, 1g in 10ml and 2g in 20ml of water for injection BP and then administered intravenously for about 2-4 minutes.

Due to possible incompatibility with other solutions or anti-microbial drugs, ceftriaxone should be used with above listed infusion solutions.

Use in pregnancy & lactation

The safety of ceftriaxone in the treatment of infections during pregnancy has not been established. So it should not be given in pregnancy (particularly in the first trimester), unless absolutely indicated. Ceftriaxone is secreted in breast milk at low concentration, hence to be administered with caution in nursing mothers.

Contra-indications

Ceftriaxone is contra-indicated in patients with known hypersensitivity to ceftriaxone or other cephalosporin class of antibiotics. It is also contra-indicated in premature infants.

Warnings

Anaphylactic shock is to be borne in mind and the shock requires immediate counter measure such as intravenous epinephrine followed by glucocorticoid.

In-vitro studies have shown that ceftriaxone, like other cephalosporins may displace bilirubin from serum-albumin. Ceftriaxone should therefore not be given to neonates.

Precautions

In severe renal impairment with hepatic insufficiency, ceftriaxone should be administered with caution. It should also be given with caution to patients with history of GI diseases, especially colitis. Prolonged use may also cause hyperinfection.

Side effects

Ceftriaxone is generally well tolerated, the adverse reactions being relatively infrequent, usually mild and transient, which were reversible either spontaneously or after withdrawal of the drug. However, few side effects including nausea, vomiting, diarrhoea, dizziness and fever may occur; rarely prolongation of Prothombin time, pancreatitis.

Drug interactions

No impairment of renal function or increased nephrotoxicity has been observed after simultaneous administration of ceftriaxone with diuretics e.g. frusemide or with aminoglycosides.

Storage instruction

Keep in a cool and dry place, below 30°C.

Presentation

All vial containing white to yellowish-orange, crystalline, sterile dry powder for reconstitution.

Aciphin® 250 mg Dry Powder for injection: Each vial contains Ceftriaxone Sodium USP equivalent to 250 mg Ceftriaxone for both IV & IM administration.

Aciphin® 500 mg Dry Powder for injection: Each vial contains Ceftriaxone Sodium USP equivalent to 500 mg Ceftriaxone for both IV & IM administration.

Aciphin® 1 g Dry Powder for injection: Each vial contains Ceftriaxone Sodium USP equivalent to 1 g Ceftriaxone for both IV & IM administration.

Aciphin® 2 g Dry Powder for injection: Each vial contains Ceftriaxone Sodium USP equivalent to 2 g Ceftriaxone for IV administration.

Solvent:

The solvent contains Xylone, 1% injection (Lidocaine Hydrochloride USP 1%) for intramuscular injection, and water for injection BP for intravenous injection.

Package quantities

Aciphin® 250 mg IM injection : Box containing 1 vial of dry powder equivalent to 250 mg Ceftriaxone, 1 ampoule of 2 ml Xylone, 1% injection (Lidocaine Hydrochloride USP 1%), 1 disposable syringe (5 ml/cc), 1 baby needle, 1 first aid bandage, and 1 alcohol pad.

Aciphin®, 250 mg IV injection : Box containing 1 vial of dry powder equivalent to 250 mg Ceftriaxone, 1 ampoule of 5 ml Water for injection BP, 1 disposable syringe (5 ml/cc), 1 baby needle, 1 first aid bandage, and 1 alcohol pad.

Aciphin®, 500 mg IM injection : Box containing 1 vial of dry powder equivalent to 500 mg Ceftriaxone, 1 ampoule of 2 ml Xylone, 1% injection (Lidocaine Hydrochloride USP 1%), 1 disposable syringe (5 ml/cc), 1 baby needle, 1 first aid bandage, and 1 alcohol pad.

Aciphin®, 500 mg IV injection : Box containing 1 vial of dry powder equivalent to 500 mg Ceftriaxone, 1 ampoule of 5 ml Water for injection BP, 1 disposable syringe (5 ml/cc), 1 baby needle, 1 first aid bandage, and 1 alcohol pad.

Aciphin®, 1 g IM injection : Box containing 1 vial of dry powder equivalent to 1 g Ceftriaxone, 1 ampoule of 3.5 ml Xylone, 1% injection (Lidocaine Hydrochloride USP 1%), 1 disposable syringe (5 ml/cc), 1 first aid bandage, and 1 alcohol pad.

Aciphin®, 1 g IV injection : Box containing 1 vial of dry powder equivalent to 1 g Ceftriaxone, 1 ampoule of 10 ml Water for injection BP, 1 disposable syringe (10 ml/cc), 1 butterfly needle, 1 first aid bandage, and 1 alcohol pad.

Aciphin® 2 g IV injection: Box containing 1 vial of dry powder equivalent to 2 g Ceftriaxone, 2 ampoules of 10 ml Water for injection BP, 1 disposable syringe (20 ml/cc), 1 butterfly needle, 1 first aid bandage, and 1 alcohol pad.

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