Cefone

Ceftriaxone

COMPOSITION

Cefone 250 mg IM Injection: Each vial contains 250 mg of Ceftriaxone as sterile Ceftriaxone Sodium USP.
Cefone 500 mg IM Injection: Each vial contains 500 mg of Ceftriaxone as sterile Ceftriaxone Sodium USP.
Cefone 1 g IV Injection: Each vial contains 1 g of Ceftriaxone as sterile Ceftriaxone Sodium USP.
Cefone 2 g IV Injection: Each vial contains 2 g of Ceftriaxone as sterile Ceftriaxone Sodium USP.
Lidocaine Solution: Each ampoule contains 2 ml of Lidocaine Hydrochloride BP 1% Injection for reconstitution.
Water for Injection: Each ampoule contains 10 ml sterile Water for Injection BP for reconstitution.

PHARMACOLOGY

Ceftriaxone (**Cefone**) is a third generation parenteral cephalosporin antibiotic which has potent bactericidal activity against a wide range of gram-positive and especially gram-negative organisms. Ceftriaxone (**Cefone**), like other cephalosporins and penicillins, kills bacteria by interfering bacterial cell wall synthesis. The spectrum of activity includes both aerobic and some anaerobic species. It has considerable stability against degradation by most bacterial beta-lactamases particularly those produced by gram-negative organisms. Ceftriaxone (**Cefone**) has relatively long plasma elimination half-life of approximately 8 hours, which offers single or once-daily dose of the drug.

INDICATIONS

Ceftriaxone (**Cefone**) is indicated for the treatment of the following infections when caused by susceptible organisms:

- Lower Respiratory Tract Infections
- Acute Bacterial Otitis Media
- Skin & Skin Structure Infections
- Urinary Tract Infections
- Intra-abdominal Infections
- Meningitis
- Bone and Joint Infections
- Septicemia
- Uncomplicated Gonorrhoea
- Pelvic Inflammatory Disease
- Surgical Prophylaxis

DOSAGE AND ADMINISTRATION

Adults: The usual adult daily dose is 1 to 2 g given once a day (or in equally divided doses twice a day) depending on the type and severity of infection. The total daily dose should not exceed 4 g.

- Severe Infections: 2-4 g daily, normally as a single dose every 24 hours.
- Uncomplicated Gonorrhoea: A single dose of 250 mg intramuscularly should be administered.
- Surgical Prophylaxis: A single dose of 1 g administered intravenously ½ to 2 hours before surgery is recommended.

Neonates: By intravenous infusion over 60 minutes, 20-50 mg/kg daily (max. 50 mg/kg daily).
Children: 20-50 mg/kg daily as a single dose, maximum up to 80 mg/kg as a single dose in severe infections; doses over 50 mg/kg should be given through intravenous infusion only.

- Skin and Skin Structure Infections: The recommended total daily dose is 50 to 75 mg/kg given once a day (or in equally divided doses twice a day). The total daily dose should not exceed 2 g.
- Acute Bacterial Otitis Media: A single intramuscular dose of 50 mg/kg (not to exceed 1 g) is recommended.
- Serious Miscellaneous Infections other than Meningitis: The recommended total daily dose is 50 to 75 mg/kg, given in divided doses every 12 hours. The total daily dose should not exceed 2 g.
- Meningitis: It is recommended that, the initial therapeutic dose is 100 mg/kg (not to exceed 4 g). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4 g daily) is recommended. The daily dose may be administered once a day (or in equally divided doses every 12 hours). The usual duration of therapy is 7 to 14 days.

USE IN THE ELDERLY

The recommended dosage for adults do not require modification in the case of elderly patients provided that renal and hepatic functions are satisfactory.

RENAL AND HEPATIC IMPAIRMENT

In patients with impaired renal function, there is no need to reduce the dosage of Ceftriaxone provided liver function is intact. Only in cases of pre-terminal renal failure (creatinine clearance <10 ml per minute) the daily dosage should be limited to 2 g or less. In patients with liver damage there is no need for the dosage to be reduced provided renal function is intact.

DURATION OF THERAPY

Generally, Ceftriaxone (**Cefone**) therapy should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration of therapy is 4 to 14 days. In complicated infections, longer therapy may be required.
Or as directed by the physician.

DIRECTIONS FOR USE

Reconstituted solutions retain their physical and chemical stability for six hours at room temperature (or 24 hours at 5°C). As a general rule, however, the solutions should be used immediately after preparation. The colour of Ceftriaxone (**Cefone**) solutions ranges from light yellow to amber depending on the length of storage, concentration and diluent used. This characteristic of the active ingredient is of no significance for the efficacy or tolerance of the drug.

INTRAMUSCULAR INJECTION

250 mg or 500 mg Ceftriaxone (**Cefone**) should be dissolved in 2 ml of Lidocaine Hydrochloride BP 1% Injection. The solution should be administered by deep intramuscular injection. Dosage greater than 1 g should be divided and injected at more than one site. Solutions in Lidocaine should not be administered intravenously.

INTRAVENOUS INJECTION

1 g of Ceftriaxone (**Cefone**) should be dissolved in 10 ml of Water for Injection BP or 2 g in 20 ml of Water for Injection BP.

CONTRAINDICATIONS

Ceftriaxone should not be given in patients with a history of hypersensitivity to cephalosporin antibiotics. It is contraindicated in premature infants and neonates with jaundice, hypoalbuminaemia, acidosis or impaired bilirubin binding; concomitant treatment with calcium in neonates & children.

PRECAUTIONS

Care is required when administering Ceftriaxone to patients who have previously shown hypersensitivity to penicillins or other non-cephalosporin beta-lactam antibiotics.

USE IN PREGNANCY AND LACTATION

Pregnancy Category B. Ceftriaxone should be used during pregnancy only if clearly needed. Low concentrations of Ceftriaxone are excreted in human milk; caution should be exercised when Ceftriaxone is administered to a nursing mother.

SIDE EFFECTS

Ceftriaxone has been generally well tolerated, side effects being relatively infrequent, usually mild and transient. The most common side effects are gastro-intestinal consisting mainly of diarrhoea, nausea, vomiting and stomatitis. Cutaneous reactions include maculopapular rash, pruritus, urticaria, oedema and erythema multiforme. Haematological reactions include anaemia, leucopenia, neutropenia, thrombocytopenia, eosinophilia and agranulocytosis. Headache, dizziness and transient elevations in liver function tests have been reported in few cases.

DRUG INTERACTIONS

No significant drug interactions have been observed with Ceftriaxone.

PACKAGING

Cefone 250 mg IM Injection: Each box contains one vial of Ceftriaxone 250 mg as sterile Ceftriaxone Sodium USP and one ampoule of 2 ml Lidocaine Hydrochloride BP 1% Injection in blister pack and a 5 ml sterile disposable syringe, a baby needle, an alcohol pad & a first aid bandage.
Cefone 500 mg IM Injection: Each box contains one vial of Ceftriaxone 500 mg as sterile Ceftriaxone Sodium USP and one ampoule of 2 ml Lidocaine Hydrochloride BP 1% Injection in blister pack and a 5 ml sterile disposable syringe, a baby needle, an alcohol pad & a first aid bandage.
Cefone 1 g IV Injection: Each box contains one vial of Ceftriaxone 1 g as sterile Ceftriaxone Sodium USP and one ampoule of 10 ml Water for Injection BP in blister pack and a 10 ml sterile disposable syringe, a butterfly needle, an alcohol pad & a first aid bandage.
Cefone 2 g IV Injection: Each box contains one vial of Ceftriaxone 2 g as sterile Ceftriaxone Sodium USP and two ampoules of 10 ml Water for Injection BP in a plastic tray and a 20 ml sterile disposable syringe, a butterfly needle, an alcohol pad & a first aid bandage.

Manufactured for:

SHARIF PHARMA

Sharif Pharmaceuticals Ltd.
Rupganj, Narayanganj, Bangladesh
By: Rangs Pharmaceuticals Ltd.

P12143