

Composition:

RIT 2 gm IV Injection : Each vial contains Ceftriaxone 2 gm (as sterile Ceftriaxone Sodium USP) and 2 x 10 ml Water for Injection BP for IV Injection.

Description :

RIT (Ceftriaxone) is a sterile semi-synthetic broad spectrum 3rd generation Cephalosporin antibiotic for intravenous or intramuscular administration. The bactericidal activity of Ceftriaxone results from inhibition of cell wall synthesis. Ceftriaxone has a high degree of stability in the presence of beta-lactamase, both penicillinases and cephalosporinases of gram-positive and gram-negative bacteria. RIT (Ceftriaxone), like other cephalosporins and penicillins, kills bacteria by interfering with the synthesis of the bacterial cell wall. A remarkable feature of RIT (Ceftriaxone) is its relatively long plasma elimination half-life of about 6 to 9 hours, which makes single or once-daily dosage of the drug appropriate for most patients. Ceftriaxone is not metabolized in the body. About 40-65% of a dose of Ceftriaxone is excreted unchanged in the urine; the remainder is excreted in the bile and ultimately found in the faeces as unchanged drug and microbiologically inactive compound. The drug is highly (95%) protein bound.

Indications :

RIT is indicated for the treatment of the following infections when caused by susceptible organisms-

1. Lower respiratory tract infections, particularly pneumonia
2. Renal and urinary tract infections
3. Gonococcal infections
4. Acute bacterial otitis media
5. Skin, soft tissue, bone and joint infections
6. Bacterial meningitis
7. Ear, nose and throat infections
8. Typhoid fever
9. Septicemia
10. Infections in cancer patients
11. Prevention of post-operative infections
12. Pre-operative prophylaxis of infections associated with surgery

Dosage & Administration :

Adult : By deep intramuscular injection or by intravenous injection over at least 2-4 minutes or by intravenous infusion, 1 gm daily; 2-4 gm daily in severe infections; intramuscular doses over 1 gm divided between more than one site.

Neonate : By intravenous infusion over 60 minutes, 20-50 mg/kg daily (max. 50 mg/kg daily).

Infant and child under 50 kg : By deep intramuscular injection or by intravenous injection over 2-4 minutes or by intravenous infusion, 20-50 mg/kg daily; up to 80 mg/kg daily in severe infections; doses of 50 mg/kg and over by intravenous infusion only; 50 kg and over, adult dose.

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 gm at induction, Preparation of injections and direction for reconstitution of powder :

For intramuscular injection : 250 mg or 500 mg should be dissolved in 2 ml of 1% Lidocaine HCl Injection BP or 1 gm in 3.5 ml of 1% Lidocaine HCl Injection BP.

For intravenous injection : 250 mg or 500 mg should be dissolved in 5 ml of Water for Injection BP or 1 gm in 10 ml of Water for Injection BP or 2 gm in 20 ml of water for Injection BP.

Use the solution immediately after reconstitution of powder. The reconstituted solution should be used within 6 hours if kept in room temperature or within 24 hours if refrigerated below 50C temperature.

Side-effects :

Generally Ceftriaxone is well tolerated. However, few side-effects including nausea, vomiting, diarrhoea, dizziness and fever may occur.

Contraindications :

Ceftriaxone is contraindicated in patients with known allergy to ceftriaxone, other cephalosporins or penicillins.

Use in pregnancy and lactation :

Pregnancy : The safety of Ceftriaxone in the treatment of infection during pregnancy has not been established. Ceftriaxone should only be used during pregnancy if the likely benefit outweighs the potential risk to the fetus or the mother.

Lactation : Ceftriaxone is excreted in breast milk at low concentrations. Therefore, caution should be exercised when Ceftriaxone is administered to a nursing mother.

Drug Interaction :

No drug interactions have yet been reported.

Overdosage :

There is no specific antidote. Treatment of overdosage should be symptomatic.

Storage :

Store below 300C, Protect from light & keep out of the reach of children.

Commercial Pack :

RIT 2 gm IV Injection : Combipack of 1 vial containing 2 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 2 ampoule of 10 ml Water for Injection BP and a 20 ml sterile disposable syringe and a butterfly needle.