Trizon

IM/IV Injection

Ceftriaxone

Composition
Trizon Intramuscular/Intravenous Injection
Trizon 250 mg: Each vial contains Ceftriaxone 250 mg (as sterile Ceftriaxone Sodium USP).
Trizon 500 mg: Each vial contains Ceftriaxone 500 mg (as sterile Ceftriaxone Sodium USP).
Trizon 1g: Each vial contains Ceftriaxone 1 g (as sterile Ceftriaxone Sodium USP).
Trizon 2g IV: Each vial contains Ceftriaxone 2 g (as sterile Ceftriaxone Sodium USP).
Lidocaine Solution: Each ampoule contains 2 ml or 3.5 ml of 1% Lidocaine injection for reconstitution.
Water for Injection: Each ampoule contains 5 ml or 10 ml sterile Water for injection BP for reconstitution.

Pharmacology
Trizon (Ceftriaxone) has potent bactericidal activity against a wide range of gram-positive and especially gram-negative organisms. It is a third-generation parenteral cephalosporin antibiotic which has excellent gram-negative activity. Trizon (Ceftriaxone), 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. Trizon (Ceftriaxone) has relatively long plasma elimination half-life of approximately 8 hours, which offers single or once-daily dosage of the drug.

Indication
Trizon is indicated for the treatment of the following infections when caused by susceptible organisms:
- Lower Respiratory Tract Infections
- Acute Otitis Media
- Skin & Skin Structure Infections
- Urinary Tract Infections
- Intra-Abdominal Infections
- Meningitis
- Bone and Joint Infections
- Septicemia
- Uncomplicated Gonorrhea
- Pelvic Inflammatory Diseases
- Surgical Prophylaxis

Dosage and administration
Route of 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 upto 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 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 dosages for adults do not require modification in the case of elderly patients provided that renal and hepatic function 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) should the daily dosage 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, Trizon (Ceftriaxone) 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.
Directions for use
Tolerance test of this medicine should be examined before administration into the body and it should be administered over a duration of 2-4 minutes. Reconstituted solutions retain their physical and chemical stability for six hours at room temperature (or 24 hours at 50C). As a general rule, however, the solutions should be used immediately after preparation. It ranges in colour from pale yellow to amber, depending on the concentration and the length of storage. 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 Trizon should be dissolved in 2 ml of 1% Lidocaine Injection BP, or 1 g in 3.5 ml of 1% Lidocaine Injection BP. The solution should be administered by deep intramuscular injection. Dosages greater than 1 g should be divided and injected at more than one site.
Solutions in Lidocaine should not be administered intravenously.
Intravenous Injection: 250 mg or 500 mg Trizon should be dissolved in 5 ml of Water for Injection BP or 1 g 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 contra-indicated 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.

Side effects
Common 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 loose stools, diarrhoea , nausea, vomiting, stomatitis and glossitis. Cutaneous reactions include maculopapular rash, pruritus, urticaria, oedema and erythema multiforme. Haematological reactions include anaemia, leucopenia, neutropenia, thrombocytopenia, eosinophilia, agranulocytosis. Headache, dizziness, drug fever and transient elevations in liver function tests have been reported in a few cases.
Rare side effects: Bronchospasm, glycosuria, haematuria, oedema.

Adverse Drug Reaction
Convulsion may occur.

Use in Pregnancy & 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.

Use in Children & Adolescents
In vitro studies have shown that ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. Ceftriaxone should not be administered to hyperbilirubinemic neonates, especially prematures.

Drug interactions
No significant drug interactions have been observed with Ceftriaxone.

Overdose
In the case of overdosage, drug concentration would not be reduced by hemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdose should be symptomatic.

Storage
Store below 30^0 C and dry place, protected from light.
Keep all medicines out of reach of children.

Packing
Trizon IM injection
Trizon 250 mg: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 250 mg and one 2 ml ampoule of 1% Lidocaine injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (5ml), baby needle, alcohol pad and first aid bandage.
Trizon 500 mg: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 500 mg and one 2 ml ampoule of 1% Lidocaine injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (5ml), baby needle, alcohol pad and first aid bandage.
Trizon 1 g: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 1 g and one 3.5 ml ampoule of 1% Lidocaine injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (5ml), alcohol pad and first aid bandage.
Trizon IV injection
Trizon 250 mg: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 250 mg and one ampoule of 5 ml water for injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (5ml), alcohol pad and first aid bandage.
Trizon 500 mg: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 500 mg and one ampoule of 5 ml water for injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (5ml), alcohol pad and first aid bandage.
Trizon 1 g: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 1 g and one ampoule of 10 ml water for injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (10ml), butterfly needle, alcohol pad and first aid bandage.
Trizon 2 g: Each box contains one vial of Ceftriaxone (as sterile Ceftriaxone sodium USP) 2 g and two ampoules of 10 ml water for injection in blister pack. It also contains a complementary pouch comprised of disposable syringe (20ml), butterfly needle, alcohol pad and first aid bandage.

* Further information is available on request.

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Manufactured by:
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