350 mg equivalent of ceftriaxone according to the amount of diluent indicated below. If required, more dilute solutions could be utilized. As with all intramuscular preparations, Ceftriaxone Sodium should be injected well within the body of a relatively large muscle; aspiration helps to avoid unintentional injection into a blood vessel.

Vial Dosage Size 500 mg, 1 g Amount of Diluent to be Added 250 mg/ml, 350 mg/ml 1.8 ml 1.0 ml 3.6 ml 2.1 ml

Intravenous Administration:

Ceftriaxone Injection IP should be administered intravenously by infusion over a period of 30 minutes. Concentrations between 10 mg/ml and 40 mg/ml are recommended; however, lower concentrations may be used if desired. Reconstitute vials with an appropriate IV diluent. Vial Dosage Size Amount of Diluent to be Added 500 mg 4.8 ml 1 g 9.6 ml after reconstitution, each 1 ml of solution contains approximately 100 mg equivalent of ceftriaxone. Withdraw entire contents and dilute to the desired concentration with the appropriate IV diluent.

Administration in hepatic and renal impairment.

A reduction in dosage of ceftriaxone may be necessary in patients with severe renal impairment (creatinine clearance below 10 ml/minute), in whom the daily dose should not exceed 2 g In patients undergoing dialysis, and in those with both renal and hepatic impairment, plasma concentrations of ceftriaxone should be monitored to determine whether dose adjustment is needed.

Adverse Effects and Precautions

Changes in bowel flora may be more marked than with cefotaxime because of the greater biliary excretion of ceftriaxone; diarrhoea may occur more often, especially in children. Biliary sludge or pseudolithiasis due to a precipitate of calcium ceftriaxone has been seen occasionally in patients given ceftriaxone. Similarly, deposition of the calcium salt has occurred rarely in theurine. Isolated cases of death in term or premature neonates have been associated with precipitation of calcium ceftriaxone in lungs and kidneys, and in some of these cases a calcium-containing product has been given by a different route or line, or at a different time. US licensed product information therefore contra-indicates the use of ceftriaxone within 48 hours of products or solutions containing calcium, particularly in neonates.

Ceftriaxone is highly protein bound and is able to displace bilirubin from albumin binding sites, causing hyperbilirubinaemia; its use should be avoided in jaundiced neonates. Neutropenia has been reported with most cephalosporin's; a complex mechanism has been attributed to that associated with ceftriaxone. There have been rare reports of fatal haemolysis associated with ceftriaxone. Although ceftriaxone has an *N*-methylthiotriazine ring rather than an *N*methylthiotetrazole side-chain, it might still have the potential to cause hypoprothrombinaemia.

Interactions

Ceftriaxone has an *N*-methylthiotriazine side-chain and may have the potential to increase the effects of anticoagulants and to cause a disulfiram-like reaction with alcohol.

Unlike many cephalosporin's, probenecid does not affect the renal excretion of ceftriaxone.

Interaction with Calcium

Two *in vitro* studies, one using adult plasma and the other neonatal plasma from umbilical cord blood have been carried out to assess interaction of ceftriaxone and calcium. Ceftriaxone concentrations up to 1 mm (in excess of concentrations achieved *in vivo* following administration of 2 grams ceftriaxone infused over 30 minutes) were used in combination with calcium concentrations up to 12 mm (48 mg/dL). Recovery of ceftriaxone from plasma was reduced with calcium concentrations of 6 mm (24 mg/dL) or higher in adult plasma or 4 mm (16 mg/dL) or higher in neonatal plasma. This may be reflective of ceftriaxone-calcium precipitation.

PREGNANCY

Pregnancy Category B:

Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryotoxicity, fetotoxicity or teratogenicity. In primates, no embryotoxicity or teratogenicity was demonstrated at a dose approximately 3 times the human dose.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

NURSING MOTHERS

Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when ceftriaxone injection IP is administered to a nursing woman.

OVERDOSAGE

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

Storage: -Store below 25°C protected from light and moisture.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: -Each pack contain 250mg/500mg/1g/2g of Ceftriaxone Injection I.P. in a vial and sterile Water for injection IP

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
© ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhivandi, Mumbai - 421302
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For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

Rx Ceftriaxone Injection I.P.

AMERICAN AONE Injection

250mg/500mg/1g/2g

FOR I.M./I.V. USE ONLY

Composition:-

Each Vial Contains:-

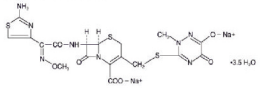
Ceftriaxone Sodium (Sterile) I.P.

Eq. to anhydrous Ceftriaxone 250 mg/500 mg/1000 mg/2000mg

Description

Ceftriaxone Injection IP is a sterile, semisynthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration. Ceftriaxone sodium *(6R ,7 R)-7 -[[(Z)- (2-aminothiazol-4-yl)(methozymino)acetyliamino]- 3-[[(2-methyl-6-oxido-5-ozo-2,5-dihydro-1,2,4-triaini-3-yl)* sulphanyl]methy1]-8-oxo-5-thia-l-azabicyclo[4.2.0]oct-2-ene-2-carboxylate hemiheptahydrate.

The chemical formula of ceftriaxone sodium is $C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3.5H2O$. It has a calculated molecular weight of 662 and the following structural formula:



Ceftriaxone sodium

Ceftriaxone Injection IP is a white to yellowish-orange crystalline powder which is readily soluble in water, sparingly soluble in methanol and very slightly soluble in ethanol. The colour of ceftriaxone Injection IP solutions ranges from light yellow to amber, depending on the length of storage, concentration and diluent used.

PHARMACOLOGY

Pharmacokinetics

Ceftriaxone demonstrates nonlinear dose-dependent pharmacokinetics because of its protein binding; about 85 to 95% is bound to plasma proteins depending on the concentration of ceftriaxone. Mean peak plasma concentrations of about 40 and 80 micrograms/ml have been reported 2 hours after intramuscular injection of 0.5 and 1 g of ceftriaxone respectively. The plasma half-life of ceftriaxone is not dependent on the dose and varies between 6 and 9 hours; it may be prolonged in neonates. The half-life does not change appreciably in patients with moderate renal impairment, but it may be prolonged in severe impairment especially when there is also hepatic impairment. Ceftriaxone is widely distributed in body tissues and fluids. It crosses both inflamed and non-inflamed meninges, generally achieving therapeutic concentrations in the CSF. It crosses the placenta and low concentrations have been detected in breast milk. High concentrations are achieved in bile. About 40 to 65% of a dose of ceftriaxone is excreted unchanged in the urine, principally by glomerular filtration; the remainder is excreted in the bile and is ultimately found in the faeces as unchanged drug and microbiologically inactive compounds.

Metabolism and Action

Ceftriaxone is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Ceftriaxone has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative and Gram-positive bacteria.

Dosage and Administration

Ceftriaxone is a third-generation cephalosporin antibacterial used similarly to cefotaxime for the treatment of susceptible infections. They include chancroid, endocarditis, gastro-enteritis (invasive salmonellosis; shigellosis), gonorrhoea, Lyme disease, meningitis (including meningococcal meningitis prophylaxis), pneumonia, septicaemia, syphilis, typhoid fever, and Whipple's disease. It is also used for surgical infection prophylaxis.Ceftriaxone is given as the sodium salt by slow intravenous injection over at least 2 to 4 minutes, by intermittent intravenous infusion over at least 30 minutes, or by deep intramuscular injection. If more than 1 g is to be injected intramuscularly then the dose should be divided between more than one sites. Doses are expressed in terms of the equivalent amount of ceftriaxone;. The usual adult dose is 1 to 2 g daily as a single dose or in two divided doses; in severe infections up to 4 g daily may be given. Doses for infants and children (under 50 kg) are 20 to 50 mg/kg once daily; for severe infections up to 80 mg/kg daily may be given. In neonates, the maximum dose should not exceed 50 mg/kg daily; intravenous doses in neonates should be given over 60 minutes. Doses above 50 mg/kg should be given by intravenous infusion only.

A single intramuscular dose of 250 mg is recommended for the treatment of uncomplicated gonorrhoea. For surgical infection prophylaxis, a single dose of 1 g may be given 0.5 to 2 hours before surgery; a 2-g dose is suggested before colorectal surgery. For the prevention of secondary cases of meningococcal meningitis, a single intramuscular dose of 250 mg may be used for adults and 125 mg for children.

Directions for use:

Intramuscular administration:

Reconstitute Ceftriaxone Injection IP powder with the appropriate diluent ceftriaxone sodium Inject diluent into vial, shake vial thoroughly to form solution. Withdraw entire contents of vial into syringe to equal total labelled dose. After reconstitution, each 1 ml of solution contains approximately 250 mg or