human serum protein by about 83-90%.

Distribution

The volume of distribution of Ceftriaxone Sodium is 7-12 L and that of Sulbactam is 18-27.6 L. Ceftriaxone Sodium penetrates well into the extravascular spaces, tissue fluid and the synovial fluid of inflamed joints. The concentrations in most extracellular foci reach or exceed several times the MIC of most pathogens for at least 24 hours after a single administration. Ceftriaxone Sodium reaches therapeutically effective concentrations in patients with bacterial meningitis which are at least ten-fold the MICs of common pathogens such as Enterobacteriaceae, H.influenzae, Meningococci, Pneumococci and Group B Streptococci. Ceftriaxone crosses placenta and is distributed in the amniotic fluid. It is also distributed in the milk.

Metabolism and excretion

Ceftriaxone is not metabolised in the body and is eliminated unchanged via two pathways, urine and bile. 40-50% of parenterally administered dose is excreted into the urine within 48 hours as active drug. Thus, high concentrations are attained in urine, whatever is not excreted via kidney is excreted through bile. Metabolism of sulbactam is less than 25%. 70-80% of Sulbactam is excreted by the kidney biliary excretion is minimal and. renal excretion is blocked by probenecid. Sulbactam and Ceftriaxone can be removed by hemodialysis. Impaired renal function and Hepatic insufficiency: Ceftriaxone is excreted via both renal and biliary pathways therefore patients with renal failure normally require no adjustments of dose however concentration of the drug should be monitored in such patients and if there is evidence of drug accumulation then dosage adjustments should be made accordingly. Dosage adjustments are not necessary in patients with hepatic dysfunction, however in patients with both hepatic dysfunction and significant renal failure, dosage should not exceed more than 2 gm daily with close monitoring of serum concentrations.

Indications

Ceftriaxone &Sulbactam is indicated for the treatment of following infections when caused by susceptible bacteria.Meningitis ,For treatment of Nosocomial infections surgical prophylaxis ,Urinary tract infections (complicated by underlying urological abnormalities) ,Skin and soft tissue infections Like cellulites, erysepalis etc. ,Cholecystitis ,Osteomyelitis ,Sexually transmitted diseases (Gonorrhoea, Chancroid, Syphilis) ,Chronic suppurative bacterial otitis media ,Infections in dialysis unit

Contraindication

Ceftriaxone &Sulbactam is contraindicated in patients with known allergy to penicillins and cephalosporins.

Warnings

Serious or occasionally fatal anaphylactic reactions have been reported in patients receiving beta-lactam antibiotics. These reactions are more likely to occur in individuals with a history of hypersensitivity reactions to multiple allergens.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Precautions :

Transient elevations of BUN and serum creatinine have been observed, at recommended doses, the nephrotoxic potential of ceftriaxone is same as other cephalosporins. Since Ceftriaxone is excreted both via renal and bile patients with renal failure normally require no adjustment in dosage when usual doses of Ceftriaxone are administered.Dosage adjustments are not necessary in patients with hepatic dysfunction; however in patients with both renal failure and hepatic dysfunction, dosage should not exceed more than 2 g daily with close monitoring of serum concentrations.

Pregnancy

Ceftriaxone &Sulbactam drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Low concentrations of Ceftriaxone are excreted in human milk. No risk to nursing infants have been reported but caution should be exercised when ceftriaxone-sulbactam is administered to nursing women.

Paediatric use

Ceftriaxone & Sulbactam should not be administered to hyperbilirubinemic neonates, especially premature.

Mode of administration

Ceftriaxone & Sulbactam may be administered intramuscularly or intravenously.

Dosage and administration: Adults

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

Dosage regimen for (Ceftriaxone & Sulbactam) should be adjusted in patients with marked decrease in renal function (creatinine clearance of < 30ml/min) and to compensate for reduced clearance less than 15ml/min patient should receive a maximum of 500mg of sulbactam every 12 hours(maximum dose 1 gram of sulbactam)

Paediatric patients

For treatment of Skin and Soft tissue infections the recommended total daily dose (in terms of Ceftriaxone) is 50-75mg/kg given once a day or (in equally divided doses twice a day). The total daily dose should not exceed 1 gram. For treatment of acute bacterial otitis media: A single intramuscular dose of 50 mg/kg (not to exceed 1gram) is recommended. In treatment of Meningitis: The initial therapeutic dose in terms of Ceftriaxone should be 100 mg/kg (not to exceed 4 grams) Daily dose may be administered once a day or in equally divided doses 12 hourly. The usual duration of therapy is 7-14 days.For treatment of serious infections other than meningitis: Recommended total daily dose in terms of Ceftriaxone is 50-75 mg/kg given in divided doses every 12 hours. The total daily dose (in terms of Ceftriaxone) should not exceed more than 2 grams.

Storage : Store in a cool,dry , dark place .Protect from light & moisture .

Improper storage may deteriorate the product.

Presentation : Ceftriaxone & Sulbactam for injection IP is a white dry powder available in clear glass vial. 10ml 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, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib, Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in

© Copyright

WHO GMP CERTIFIED

Scan for Batch Certificate

For the use of a Registered Medical Practitioner or a Hospital or Laboratory only.

℞

Ceftriaxone & Sulbactam For Injection IP

AMERICAN AONE SB 1.5g

For IM/IV use only

Composition :

Each Vial Contains :		
Sterile Ceftriaxone Sodium eq. to anhydrous Ceftriaxone	IP	1000 mg
Sterile Sulbactam Sodium eq. to anhydrous Sulbactam	IP	500 mg

Description:

The combination of Ceftriaxone Sodium and Sulbactam Sodium available for parenteral administration. Ceftriaxone is a parenteral third-generation cephalosporin with a long elimination half-life which permits once-daily administration and a good tolerability profile.The unique molecular structure of Ceftriaxone provides the following advantages The aminothiazole -methoxyimino acyl side chain is responsible for beta-lactamase stability (more stable as compared to other third generation cephalosporins) The "triazine" ring confers greater efficacy against Neisseria, H.influenzae and Proteus mirabilis compared with such other third generations as Cefotaxime, Ceftazidime. The hydroxyl group in the triazine enhances the penetration power particularly into gram negative bacteria. Therefore rapid action and does not act as an inducer for production of beta-lactamases.The hydroxyl group is also responsible for long elimination half-life. Sulbactam is a penicillanic acid sulfone derivative and has weak antibacterial activity, but is a potent inhibitor of many plasmid-encoded and some chromosomal beta-lactamases. The combination of Ceftriaxone (3rd generation cephalosporin) and Sulbactam (beta-lactamase inhibitor) provides a solution for treatment of such bacterial infections caused betalactam resistant pathogens. Ceftriaxone has a broad spectrum of antibacterial activity is beta-lactamase stable and exhibits excellent activity against Streptococcus pneumoniae, methicillinsusceptible staphylococci, Haemophilus influenzae, Moraxella catarrhalis and Neisseria spp which are the most common cause of community acquired and hospital acquired infections

Mode of action:The bactericidal activity of Ceftiaxone & Sulbactam is due to the Ceftriaxone component and the ability of Ceftriaxone to interfere with the biosynthesis of the peptidoglycan component of the bacterial cell wall by binding to and inactivating penicillin-binding proteins (PBPs). Ceftriaxone induces filamentation in Escherichia coli and Pseudomonas aeruginosa, it binds primarily to PBP 3 which is responsible for formation of cross-wall or septum of dividing bacilli. Ceftriaxone has a high degree of stability against the beta-lactamases, both penicillinases and cephalosporinases produced by both gram -ve and gram +ve bacteria but not against chromosomally and plasmid mediated ESBL's produced by some strains of Klebsiella,Escherichia coli, Enterobacter spp and Serratia spp. Sulbactam irreversibly blocks the destruction of beta-lactam ring of Ceftriaxone by these wide variety of ESBLs and chromosomally mediated beta-lactamases by attaching to these enzymes and acting as a suicide substrate that forms a stable intermediate, rendering the enzyme inactive. Sulbactam is a broader-spectrum beta-lactamase inhibitor than clavulanic acid. Sulbactam does not induce chromosomal beta-lactamases like clavulanic acid, nor does it select for derepressed beta-lactamase-producing bacteria. Thus the full potential of Ceftriaxone against Klebsiella, pseudomonas, Escherichia coli spp is restored by addition of Sulbactam.

Microbiology :

Antimicrobial spectrum of (Ceftriaxone & Sulbactam)

The combination of Ceftriaxone Sodium and Sulbactam Sodium is active against all the organisms sensitive to Ceftriaxone.

Gram-Negative Aerobes :Acinetobacter calcoaceticus ,Enterobacter aerogenes ,Enterobacter cloacae ,Escherichia coli ,Haemophilus influenzae (including ampicillin-resistant and beta-lactamase producing strains), Haemophilus parainfluenzae ,Klebsiella oxytoca ,Klebsiella pneumoniae , Moraxella catarrhalis (including beta-lactamase producing strains) ,Morganella morganii ,Neisseria gonorrhoeae (including penicillinase - and nonpenicillinase-producing strains), Neisseria meningitidis , Proteus mirabilis ,Proteus vulgaris , Serratia marcescens

Ceftriaxone is also active against many strains of Pseudomonas aeruginosa. Many strains of the above organisms that are resistant to other antibiotics, eg, penicillins, cephalosporins and aminoglycosides, are susceptible to Ceftriaxone.

Gram-Positive Aerobes:Staphylococcus aureus (including penicillinase-producing strains and methicillin sensitive strains but not methicillin resistant strains),Staphylococcus epidermidis ,Streptococcus pneumoniae ,Streptococcus pyogenes .Viridans group streptococci

Anaerobes: Bacteroides fragilis, Clostridium species , Peptostreptococcus species.

Pharmacokinetics

Ceftriaxone &Sulbactam can be administered IM or IV.

Following intramuscular administration, peak serum concentrations of Ceftriaxone and Sulbactam are seen between 15 minutes to 2 hrs. The maximum plasma conc of Ceftriaxone after a single IM dose of 1.0 g is about 81mg/L and is reached 2-3 hrs after the dose while that of Sulbactam Sodium is 6-24 mg/L and is reached approximately 1 hr after the dose. Hence effective amount of beta-lactamases are destroyed by the time peak concentration of Ceftriaxone is reached allowing full potential of action of Ceftriaxone against ESBL producing Klebsiella , E coli spp. Serum concentrations have been shown to be proportional to the amount of dose administered.

On intravenous administration Ceftriaxone Sodium diffuses into the tissue fluid where if given in the recommended doses bactericidal concentrations are maintained for upto 24 hrs. Ceftriaxone is highly bound to