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

℞ Ceftriaxone & Sulbactam for Injection IP

ONEJECT™ SB

FOR IM / IV USE ONLY

Composition:
Each vial contains:
Ceftriaxone Sodium (Sterile) IP
Eq. to Anhydrous Ceftriaxone 1000 mg
Sulbactam Sodium (Sterile) IP
Eq. to Anhydrous Sulbactam 500 mg

PHARMACOLOGICAL CLASSIFICATION:
Cephalosporin group of antibiotics with beta-lactamase inhibitor.

INTRODUCTION:
Ceftriaxone & Sulbactam For Injection is an injectable antibacterial combination consisting of the semisynthetic antibiotic Ceftriaxone Sodium and the beta-lactamase inhibitor Sulbactam Sodium (2:1) for intravenous and intramuscular administration. It exhibits a broad spectrum of antimicrobial activity on Gram negative, Gram positive and anaerobic organisms. It is very much useful in emergency cases where other antibiotics are found ineffective because of their high degree of reliability with wider spectrum of activity. Ceftriaxone & Sulbactam For Injection exhibits antimicrobial synergy and has lower MIC than Ceftriaxone alone. Also, Sulbactam enhances the antibacterial potency of Ceftriaxone in Ceftriaxone & Sulbactam For Injection. Sulbactam sodium is a derivative of the basic penicillin nucleus. It is an irreversible betalactamase inhibitor for parenteral use only. Chemically it is sodium penicillinate sulfone.

PHARMACOLOGICAL ACTION:
Ceftriaxone exerts in vitro activity against a wide range of Gram-negative and Gram-positive micro-organisms. Ceftriaxone is highly stable to most beta-lactamases, both the penicillinases and cephalosporinases, of Gram-positive and Gram-negative bacteria. The bactericidal activity of ceftriaxone results from inhibition of bacterial cell wall synthesis.
Sulbactam, a derivative of the basic penicillin nucleus, is a beta-lactamase inhibitor. It is used to increase the antibacterial spectrum of penicillins and cephalosporins against penicillinase-producing and beta-lactamase-producing organisms such as *Staphylococcus aureus*, *H. flu, Moraxella catarrhalis* that are resistant to ampicillin alone. Sulbactam does not improve enterococcal activity of ampicillin.

PHARMACOKINETICS:
Immediately after completion of a 5-minute intravenous infusion of it, peak serum concentrations of Ceftriaxone and sulbactam are attained. Ceftriaxone serum levels are similar to those produced by the administration of equivalent amounts of ampicillin alone. The maximum plasma concentration after a single intramuscular dose of 1 g is about 81 mg/l and is reached in 2 to 3 hours after administration. The area under the plasma concentration-time curve after intramuscular administration is equivalent to that after intravenous administration of an equivalent dose, indicating 100% bioavailability of intramuscularly administered ceftriaxone.

INDICATIONS:
It is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory tract infections (Upper and Lower), Urinary tract infections (Upper and Lower), Peritonitis, Cholecystitis, Cholangitis, and other Intra abdominal infections, Septicemia, Meningitis, Pelvic inflammatory disease, Endometritis, Gonorrhoea and other infections of the Genital tract, Skin and soft tissue infections, Bone and joint infections.

CONTRA-INDICATIONS:
The use of it is contraindicated in individuals with a history of hypersensitivity reactions to any of the penicillins and to the cephalosporin-class of antibiotics.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children over twelve: 1-2 g Ceftriaxone & Sulbactam once daily (every 24 hours).
In severe infections and in cases in which the pathogens are only moderately sensitive to ceftriaxone, the daily dosage may be increased to 4 g administered daily.

Infants and young children may receive from 20-80 mg per kg body-mass daily; depending on the severity of the infection, usually 12-24 hourly.

Administration: IV: For intermittent infusion, reconstituted the drug with appropriate amount of 5% Dextrose in Water, 0.9% Sodium Chloride Injection or Sterile Water for Injections and then diluted to 20 ml with the same solution followed by administered over 15-60 min.

For IV injection, the drug should be administered over a minimum of 3 min.
IM: Sterile Water for Injections should be used for constitution. For a concentration of Ceftriaxone of 250 mg/ml or larger, a 2-step dilution is required using Sterile Water for Injections followed by 2% lidocaine to approximate a 0.5% lidocaine solution.

WARNINGS:
• Pseudomembranous colitis has been reported with ceftriaxone. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of ceftriaxone. Super infections with non-susceptible micro-organisms may occur.
• Shadows that have been mistaken for gallstones have been detected by sonograms of the gallbladder, usually following higher than the standard recommended dose.
• These shadows are, however, precipitates of calcium ceftriaxone, which disappear on completion, or discontinuation of ceftriaxone therapy. In less frequent cases, these findings have been associated with symptoms. In symptomatic cases, conservative non-surgical management is recommended. Discontinuation of ceftriaxone treatment in symptomatic cases should be at the discretion of the clinician.
• Studies have shown that ceftriaxone, like other cephalosporins, can displace bilirubin from serum albumin. Caution should be exercised when considering ceftriaxone treatment in hyperbilirubinemic neonates. Ceftriaxone should not be used in neonates (especially premature) at risk of developing bilirubin encephalopathy.
• During prolonged treatment the blood profile should be checked at regular intervals.
• It should be administered with caution to any patient who is penicillin sensitive or has demonstrated any other form of allergy, particularly to drugs. Serious anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen, intravenous steroids, and airway management, including incubation, should be administered.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Fixed drug eruption (FDE) has been reported with cephalosporin class formulations.
Ceftriaxone induced Stevens-Johnson Syndrome (SJS).
Local side effects: in rare cases, phlebitic reactions occurred after IV administration. This may be prevented by slow (two to four minutes) injection of the substance. Intramuscular injection without lidocaine solution is painful and contraindicated.

SPECIAL PRECAUTIONS:
Before therapy with ceftriaxone is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins or other medicines. About 10% of penicillin-sensitive patients may also be allergic to cephalosporins although the true incidence is uncertain. Great care should be taken if ceftriaxone is to be given to such patients.

Pregnancy and lactation: Safety in human pregnancy has not been established.
As ceftriaxone is excreted in the breast-milk at low concentrations, caution is advised in nursing mothers.

DRUG INTERACTIONS:
• No impairment of renal function has been observed after concurrent administration of large doses of ceftriaxone and potent diuretics (e.g. furosemide). There is no evidence that ceftriaxone increases renal toxicity of aminoglycosides. No effect similar to that of disulfiram has been demonstrated after administration of alcohol with ceftriaxone. Ceftriaxone does not contain an N-methylthiotetrazole moiety associated with possible ethanol intolerance and bleeding problems.
• The elimination of ceftriaxone is not altered by probenecid.
In an in vitro-study antagonistic effects have been observed with the combination of chloramphenicol and ceftriaxone.
• In patients treated with ceftriaxone the Coombs test may become false positive. Ceftriaxone, like other antibiotics, may result in false-positive tests for galactosemia.
• Likewise, nonenzymatic methods for the glucose determination in urine may give false-positive results. For this reason, urine-glucose determination during therapy with ceftriaxone should be done enzymatically

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENTS:
In the case of overdosage, plasma concentration would not be reduced by haemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdosage should be symptomatic.

STORAGE :
Store below 30°C. Protect from light & moisture. Do not freeze.
Keep medicine out of reach of children.

PRESENTATION:
ONEJECT SB injection is available in a vial and packed in mono carton with 10ml of Sterile Water for Injections IP.

Manufactured by :
Protech Telelinks
(A WHO-GMP Certified Co.)
Mauza Ogli, Suketi Road, Kala Amb,
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Marketed by :

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