CEFTRIAXONE SODIUM + SULBACTAM SODIUM

CEFSUL IV

1 g / 500 mg Powder for injection (IM/IV)

ANTIBACTERIAL

Formulation:
Each vial contains:
Ceftriaxone sodium USP
eq. to Ceftriaxone 1g
Sulbactam sodium USP
eq. to Sulbactam ..... 500 mg

Description: White to off white crystalline powder, filled in clear glass vial, sealed with grey coloured butyl rubber stopper and coloured flip of seal.

Clinical Pharmacology: Ceftriaxone sodium + Sulbactam sodium (Cefsul IV) 1g/500mg Powder for Injection (I.M./I.V.) is a anti-infective combination of Ceftriaxone with Sulbactam. Ceftriaxone is a broadspectrum semi-synthetic third generation cephalosporin with a potent bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria. Sulbactam is β-lactamase inhibitor.

Pharmacokinetics
Following intramuscular administration, peak serum concentrations of Ceftriaxone and Sulbactam are seen between 15 minutes to 2 hrs. The area under curve (AUC) after IM administration is equivalent to that after IV administration of an equivalent dose, indicating 100% bioavailability of intramuscularly administered Ceftriaxone sodium. Ceftriaxone is highly bound to human serum protein by about 83-90%. Ceftriaxone sodium penetrates well into the extravascular spaces, tissue fluid and the synovial fluid of inflamed joints.

Ceftriaxone crosses the placenta and is distributed in the amniotic fluid. It is also distributed in the milk.

Ceftriaxone is eliminated unchanged via two pathways, urine and bile. Metabolism of sulbactam is less than 25%. 70-80% of Sulbactam is excreted by the kidney & biliary excretion is minimal.

Indications
Ceftriaxone sodium + Sulbactam sodium (Cefsul IV) 1g/500mg Powder for Injection (I.M./I.V.) is indicated for the treatment of meningitis, nosocomial infections surgical prophylaxis, urinary tract infections (complicated by underlying urological abnormalities), skin and soft tissue infections like cellulitis, erysipelas etc., cholecystitis, osteomyelitis, sexually transmitted diseases (gonorrhea, chancroid, syphilis), chronic suppurative bacterial otitis media, infections in dialysis unit.

Dosage and Administration
The recommended adult dosage is 1.5 g to 3 g every six hours. It may be administered intravenously or intramuscularly. This 1.5 to 3 g range represents the total of Ceftriaxone content plus the sulbactam content and corresponds to a range of 1 g ceftriaxone / 500 mg sulbactam to 2 g ceftriaxone /1 g sulbactam. For children with body weights of 50 kg or more, the usual adult dosage should be used.

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.

Direction for reconstitution
Dissolve the content in sterile water for Injection. After reconstitution discard any unused portion.

Precautions
General: Transient elevations of BUN (blood urea nitrogen) and serum creatinine have been observed, at recommended doses, the nephrotoxic potential of ceftriaxone is the same as other cephalosporins.

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.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Carcinogenic studies with ceftriaxone in animals have not been performed. Ceflriaxone showed no potential mutagenic activity. Ceftriaxone produced no impairment infertility in animal studies.

Pregnancy: Teratogenic effects: Pregnancy category B.

No evidence of embryotoxicity, fetotoxicity or teratogenicity in animal studies. 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 + sulbactam is administered to nursing women.

Pediatric use: Ceftriaxone sodium + Sulbactam sodium (Cefsul IV) 1 g / 500 mg Powder for Injection (I.M. /I.V.) should not be administered to hyperbilirubinemic neonates, especially premature.

Adverse Effects:
Gastro-intestinal complaints: Loose stools/diarrhea, nausea, vomiting, stomatitis, glossitis.

Haematological changes: Eosinophilia, haematoma or bleeding, thrombocytopenia, neutropenia, leukopenia, granulocytopenia and haemolytic anaemia. Isolated cases of agranulocytosis (<500/mm) have been reported, most of them following total doses of 20 g or more.

Exanthema, allergic dermatitis, pruritus, urticaria, oedema, erythema multiforme may occur.

Other adverse effects include headaches and dizziness, increase in liver enzymes, oliguria, and increase in serum creatinine, mycosis of the genital tract, fever, shivering and anaphylactic or anaphylactoid reactions.

Local: Inflammatory reactions in the vein wall may occur after IV administration. These may be minimized by slow (2-4 minutes) injection. Intramuscular injection without lidocaine solution is painful.

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

ADR Statement: For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Storage: Store at temperatures not exceeding 25°C.

Do not freeze. Protect from light and moisture.

Keep all medicines out of reach of children.

Availability: One vial of Ceftriaxone + Sulbactam 1 g / 500 mg Powder for Injection in a carton along with an insert, box of 1's.

Registration No. DRP-XXXX

Imported and Distributed by:

BIOCARE LIFESCIENCES, INC.

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Manufactured by:

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