CLAFOCARE 1 GM

CEFOTAXIME FOR INJECTION USP 1gm

Composition :
Each vial contains:
Sterile Cefotaxime Sodium USP
Equivalent to Anhydrous Cefotaxime.....1 gm

PHARMACOLOGICAL ACTION:
Cefotaxime is a semi-synthetic cephalosporin antibiotic with a broad spectrum of activity against both Gram positive and Gram negative bacteria. Cefotaxime is bactericidal in its mode of action and has a high degree of stability in the presence of ß-lactamases. The following have been found to be sensitive to Cefotaxime in vitro :
Gram positive: Staphylococcus aureus, including certain penicillinase and non-penicillinase producing strains, Staphylococcus epidermidis, Streptococcus pyogenes (Group A ß-haemolytic streptococci), Straptococcus agalactiae (Group B streptococci) (Note: most strains of enterococci, eg, S.faecalis are resistant),Streptococcus pneumoniae.
Gram negative: Citrobacter species, Enterobacter species, Escherichia coli, Haemophilus influenzae (including ampicillin-resistant H influenzae), Klebsiella species (including K pneumoniae), Neisseria gonorrhoeae, Proteus mirabilis, Morganella (Proteus) morganii, Proteus rettgeri, Proteus vulgaris, Providencia species, Salmonella species, (including S. typhi), Serratia species, Shigella species. Cefotaxime and aminoglycosides have been shown to be synergistic in vitro against some strains of P. aeruginosa.
Anaerobes: Bacteroides species, Clostridium species (Note: most strains of C. difficile are resistant), Peptococcus species, PeptostrepTococcus species.

HUMAN PHARMACOLOGY:
I.M. Injection
Following I.M. Injection of doses of 0.25 g, 0.5 g and 1 g, peak levels were recorded at 30 minutes. The level increased according to the dose and was approximately 24 µg/mL after the 1 g injection. Urinary excretion in the 24 hours after injection was 50 - 60% of the dose administered. It was 44 - 55% in the first 6 hours after I.M. Injection. The serum protein binding of the drug was approximately 38%
I.V. Injection
The initial phase half-lives for whole blood and plasma are 4.5 and 8 minutes respectively. Terminal phase half-lives for whole blood and plasma are 1.3 and 2.2 hours respectively. 65 to 90% of the administered dose is excreted in the urine and 7-9.5% in the faeces. Most of the dose is excreted within 4 hours of dosing. Approximately 20-36% of an I.V. administered dose of cefotaxime is excreted by the kidney as unchanged cefotaxime and 15-25% as the desacetyl derivative, the major metabolite. Desacetylcefotaxime has been shown to contribute to the bactericidal activity. Two other urinary metabolites (M2 & M3) account for 20 - 25% They lack bactericidal activity. After a single I.V. injection of Cefotaxime 1 g serum protein binding of the drug is approximately 44%
I.V. Infusion
Loading dose of 0.5 g, 1 g and 2 g administered over 15 minutes followed by sustaining infusions of 0.5 g, 1 g and 2 g per hour produces mean peak serum levels of 41.93 and 160 µg/mL respectively. The mean terminal half-life is 75 ±7 minutes. 63 ±9% of the administered dose is excreted through the kidneys within 24 hours. Serum protein binding is approximately 35%

INDICATIONS:
Cefotaxime is indicated for use primarily in the treatment of infections of the genito urinary, gastrointestinal and respiratory tracts, in the skin and soft tissues and meningitis in children caused by susceptible strains of the following organisms: Staphylococcal infections: (including infections caused by both penicillinase-producing and non-penicillinase-producing strains): abscess, furunculosis, bronchitis and impetigo.
Streptococcal infections: (both ß-haemolytic and group D streptococci), cellulitis, pneumonia, follicular tonsillitis, otitis media, pharyngitis, sinusitis, scarlet fever, septic sore throat, urinary tract infections (Enterococci) and meningitis in children.
Pneumococcal infections: Lobar pneumonia, bronchitis, cellulitis and otitis media. Haemophilus influenzae infections: Otitis media, laryngotracheobronchitis and meningitis in children. E coli infections: Lobar pneumonia, urinary tract infections and meningitis in children.
Shigella infections: Bacillary dysentery Salmonella infections: Enteritis Sensitive strains of Pseudomonas aeruginosa : Sepsis Gonococcus: Gonorrhoea Neisseria Meningitidis: Meningitis in children. Bacteriological studies to determine the causative organisms and their sensitivity to Cefotaxime should be performed. Prophylactic uses The administration of Cefotaxime perioperatively may reduce the incidence of certain post-operative infections in patients undergoing surgical procedures that are classified as potentially contaminated. The minimum effective dose has been found to be 1 g Cefotaxime 30-90 minutes prior to surgery.

CONTRA-INDICATIONS: Cefotaxime is contra-indicated in subjects allergic to cephalosporins.
WARNING : Cefotaxime must be used with caution in penicillin-sensitive subjects. Strict medical supervision is required throughout the treatment.

DOSAGE AND DIRECTIONS FOR USE:
Intravenous and Intramuscular Injections :
Dissolve Cefotaxime in Water for Injections BP as shown below. Shake well until dissolved and then withdraw the entire contents of the vial into the syringe and use immediately.

Vial Size	Volume of Water for Injection to be added
500 mg	2 ml
1 g	4 ml

Intravenous Infusion :
Cefotaxime may be administered by intravenous infusion using 1g vials. 1 - 2 g are dissolved in 40 - 100 mL of Water for Injections BP or in the infusion fluids listed under "Stability in Infusion Fluids" The prepared infusion solutions should be administered over 20 - 60 minutes.
Dosage, route of administration and frequency of injections depend on the nature and severity of the infection, the condition of the patient, and the sensitivity of the pathogens to cefotaxime.
Adults:
Usual dose 2 g daily, in 2 x 1 g injections. Severe cases may be given 3 - 4 g daily in 2 - 4 administrations. Very severe cases may be given up to 12 g I.V.
Neonates, Infants and Children :
Neonates :
The following dosage schedule is recommended :

0 - 1 week of age	-	50 mg/kg I.V. q 12 h
1 - 4 weeks of age	-	50 mg/kg I.V. q 8 h

It is not necessary to differentiate between premature and normal-gestational age infants.
Children and Infants :
Usual daily dose 50 - 100 mg/kg body mass in 2 - 4 injections. In exceptional cases up to 200 mg/kg per day may be given.
In Renal Failure :
The dosage of Cefotaxime should be reduced by half in patients with creatinine clearances of less than 20 ml/minute. The dosage interval should not be modified.

WARNING :
Use freshly prepared solution. Do not mix Cefotaxime with another antibiotic in the same syringe or infusion.
Stability in infusion fluids: The stability of Cefotaxime in a concentration of 1 g per 250 mL in the following infusion fluids is satisfactory for 24 hours in a refrigerator or 12 hours at a temperature not exceeding 23°C. 0.9% sodium chloride, 5% dextrose, Ringer's solution.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS :
It has not yet been established whether the product is safe in pregnancy, although animal studies have not shown any teratogenic effects.

PRECAUTIONS :
- Stop the treatment should any allergic reaction appear
- Adapt the dosage in cases of organic or functional renal failure as mentioned under "Dosage and Directions for Use"
- Any combination with potentially nephrotoxic drugs and powerful diuretics should be taken into account in assessing the risks involved in such drug combinations.

SIDE EFFECTS :
Local Reactions : Deep phlebitis after I.V. Injection has been reported.
General Reaction : Skin eruptions, fever, eosinophilia, neutropenia, transient leucopenia and haemolytic anaemia. Granulocytopenia and agranulocytosis may develop during treatment with cefotaxime, particularly if given over long periods. For cases of treatment lasting longer than ten days, blood counts should therefore be monitored. Cases of diarrhoea have been recorded. The onset of diarrhoea may indicate the appearance of pseudomembraneous colitis, the diagnosis of which should be confirmed by colonoscopy. This occurrence requires immediate cessation of administration and treatment with appropriate specific antibiotic therapy. Temporary elevation of transaminases and alkaline phosphatases have been recorded.
Interaction with Laboratory Tests: A false positive reaction can occur on testing for glucose in the urine with reducing substances, but this can be avoided with use of methods that are specific to gluco-oxidase. Development of a positive Coombs'test may occur during treatment with cefotaxime.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :
Treatment should be symptomatic and supportive. In case of overdose, especially in renal impairment, there is a risk of reversible metabolic encephalopathy.

STORAGE INSTRUCTIONS :
Store away from light in a cool place below 25°C.

KEEP OUT OF THE REACH OF CHILDREN.

PRESENTATION :
CLAFOCARE 1 GM available in a glass vial.

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