ROCICARE 1 GM

CEFTRIAXONE FOR INJECTION USP 1 gm

COMPOSITION :
Each vial contains:
Ceftriaxone Sodium USP
Equivalent to Anhydrous Ceftriaxone.....1 gm

PHARMACOLOGY :
Ceftriaxone is a broad spectrum third generation cephalosporin with a long plasma elimination half life of approximately 8 hours in normal adults.

MECHANISM :
Ceftriaxone inhibits mucopeptide synthesis in the bacterial cell wall, making it defective and osmotically unstable. The drug is usually bactericidal, depending on organism susceptibility, dose, tissue, concentrations and the rate at which organisms are multiplying. It is more effective against rapidly organisms forming cell walls.

INDICATIONS :
Lower respiratory tract infections caused by Streptococcus pneumoniae, Staphyloccus aureus. Haemophilus influenzae, H.parainfluenzae, Klebsiella pneumoniae, Serratia marcescens, Escherichia coli, E. aerogenes, Proteus mirbilis. Skin and skin structure infections caused by S. aureus, S. epidermidis, Streptococcus pyogenes, Viridans group streptococci, E.coli, Enterobacter cloacae, K. oxytoca, K. pneumoniae, P. mirabilis, Pseudomonas aeruginosa, Morganella morganii, S. marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis, Peptostreptococcus sp.
Urinary tract infections (complicated and uncomplicated) caused by E.coli, P.mirabilis, P.vulgaris, Morganella morgani and Klebsiella sp (including K pneumoniae). Uncomplicated gonorrhea (cervical/urethral and rectal) caused by Neisseria gonorrhoeae, including both penicillinase/nonpenicillinase-producing strains (considered treatment of choice) and pharyngeal gonorrhea caused by non-penicillinase-producing strains of N.gonorrhoeae.
Pelvic inflammatory disease caused by N. gonorrhoeae. Bacterial speticemia caused by S. aureus, S.pneumoniae. E.col. H. influenzae and K.pneumoniae.
Bone and joint infections caused by S.aureus, S. pneumoniae, Streptococcus sp (excluding enterococci), E.coli, P. mirabilis, K. pneumoniae, S. pneumoniae, Streptococcus and Enterobacter sp.
Intra-abdominal infections caused by E.coli, K.pneumoniae, B. fragilis, Clostridium sp (most strains of C. difficile are resistant), Peptostreptococcus sp. Meningitis caused by H.influenzae, N. meningitis and S. pneumoniae. Has been used successfully in a limited number of cases of meningitis and shunt infections caused by S. epidermidis and E.coli.
Prophylaxis : The use of a single preoperative dose may reduce the incidence of post operative infections in patients undergoing surgical procedures classified as contaminated (eg. Vaginal or abdominal hysterectomy) and in surgical patients for whom infection at the operative site would present serious risk (eg. Coronary artery bypass surgery). Ceftriaxone is as effective as cefazolin in preventing infection following coronary artery bypass surgery.

ADMINISTRATION AND DOSAGE :
Administer IV or IM. Continue for at least 2 days after signs and symptoms of infection have disappeared. Usual duration is 4 to 14 days; in complicated infections, longer therapy may be required. For S.pyogenes, continue for at least 10 days.
Adults : Usual daily dose is 1 to 2 g once a day (for in equally divided doses twice a day) depending on type and severity of infection. Do not exceed total daily dose of 4 g. Uncomplicated gonococcal infections - Give a single IM dose of 250 mg. Surgical prophylaxis - Give a single 1 g dose 1/2 to 2 hours before surgery.
Children : To treat serious infections other than meningitis, administer 50 to 75 mg/kg/day (not to exceed 2 g) in divided doses every 12 hours. Meningitis -100 mg/kg/day (not to exceed 4 g). Thereafter, a total daily dose of 100mg/kg/day (not to exceed 4 g/day) is recommended. May give daily dose once per day. In Skin and skin structure infections - give 50 to 75 mg/kg once daily (or in equally divided doses twice daily), not to exceed 2 g.
CDC (1993 Sexually Transmitted Disease Treatment Guidelines, Morbidity and Mortality schedules for chancroid, gonorrhea and acute pelvic inflammatory disease (PID) :
Chancroid (Haemophilus ducreyi infection) - 250 mg IM as a single dose.
Gonococcal infections - Uncomplicated : 125 mg IM once plus doxycycline.
Conjunctivitis : 1 g IM single dose.
Disseminated : 1 g IM or IV every 24 hours.
Meningitis/Endocarditis : 1 to 2 g IV every 12 hours for 10 to 14 days (meningitis) or for at least 4 weeks (endocarditis).
Children : (<45 kg) : With bacteremia or arthritis, use 50 mg/kg (maximum, 1g) IM or IV in a single dose for 7 days. For meningitis, increase duration to 10 to 14 days and maximum dose to 2 g.
Infants : 25 to 50 mg/kg/day IV or IM in a single daily dose, not to exceed 125 mg. For disseminated infection, continue for 7 days, with a duration of 7 to 14 days with documented meningitis.
Acute PID (ambulatory) – 250 mg IM plus doxycycline.
Pregnancy :Use only when potential benefits outweigh potential hazards to the foetus.
Lactation : Excreted in small quantities in breast milk & hence, use only when the benefits outweigh potential hazards to the neonate.

CONTRAINDICATIONS :
Solutions in lignocaine should not be administered intravenously. Ceftriaxone should not be given to patients with a history of hypersensitivity to cephalosporin antibiotics.
Ceftriaxone should not be given to neonates with jaundice or those who are hypoalbuminaemic or acidotic or have other conditions, such as prematurity, in which bilirubin binding is likely to be impaired.

WARNINGS :
Cross-allergenicity with penicillin : Administer cautiously to penicillin-sensitive patients. There is evidence of partial cross-allergenicity; cephalosporins cannot be
assumed to be an absolutely safe alternative to penicillin in the penicillin-allergic patient. The estimated incidence of cross-sensitivity is 5% to 16%; however, it is possibly as low as 3% to 7%.
Serum sickness-like reactions (erythema multiforme or skin rashes accompanied by polyarthritis, arthralgia and, frequently fever) have been reported; these reactions usually occur following a second course of therapy. Signs and symptoms occur after a few days of therapy and resolve a few days after drug discontinuation with no serious sequelae. Antihistamines and corticosteroids may be of benefit in managing symptoms.
Seizures : Severe cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage is not reduced. If seizures associated with drug therapy occur, discontinue the drug. Anticonvulsant therapy can be given if clinically indicated.

SIDE EFFECTS:

Ceftriaxone has been generally well tolerated. Adverse reactions are usually mild and transient.

The most common side-effects are gastrointestinal, consisting mainly of loose stools and diarrhoea or, occasionally, nausea and vomiting, stomatitis and glossitis. Cutaneous reactions, including maculopapular rash or exanthema, pruritus, urticaria, oedema and allergic dermatitis have occurred. Isolated cases of severe cutaneous adverse reactions (erythema multiforme, Stevens Johnson Syndrome and Lyell's Syndrome/toxic epidermal necrolysis) have been reported.

Haematological reactions have included anaemia (all grades), haemolytic anaemia, leucopenia, neutropenia, thrombocytopenia, eosinophilia, agranulocytosis and positive Coombs' test. Regular blood counts should be carried out during treatment. Ceftriaxone has rarely been associated with prolongation of prothrombin time. Headache and dizziness, drug fever, shivering and transient elevations in liver function tests have been reported in a few cases. Other rarely observed adverse reactions include glycosuria, oliguria, haematuria, increase in serum creatinine, mycosis of the genital tract and anaphylactic-type reactions such as bronchospasm.

Very rarely, reversible symptomatic urinary precipitates of calcium ceftriaxone have occurred after ceftriaxone administration. Patients who are very young, immobilised or who are dehydrated are at increased risk. There have been a few reports of anuria and renal impairment following this reaction.

Shadows which have been mistaken for gallstones, but which are precipitates of calcium ceftriaxone, have been detected by sonograms. These abnormalities are commonly observed after an adult daily dose of two grams per day or more, or its equivalent in children. At doses of two grams a day or above these biliary precipitates may occasionally cause symptoms. Should patients develop symptoms, non-surgical management is recommended and discontinuation of ceftriaxone should be considered. The evidence suggests biliary precipitates usually disappear once ceftriaxone has been stopped. The risk of biliary precipitates may be increased by treatment duration greater than 14 days, renal failure, dehydration or total parenteral nutrition. There have been isolated reports of pancreatitis although a causal relationship to immediately after administration but is usually well tolerated and transient. Local phlebitis has occurred rarely following intravenous administration but can be minimised by slow injection over at least 2-4 minutes

OVERDOSAGE:

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

COAGULATION ABNORMALITIES:

Alterations in prothrombin times (PT) occur rarely in patients treated with ceftriaxone.

HYPERSENSITIVITY:

Reactions range from mild to life-threatening. Before therapy is instituted, inquire about previous hypersensitivity reactions to cephalosporins and penicillins. If a hypersensitivity reaction occurs discontinue the drug and institute appropriate therapy.

RECONSTITUTION:

Reconstitution of Ceftriaxone with Sterile Water for Injections BP, 10ml			
	Vial/Bottle dosage	Amount of diluent	Resultant
	Size	to add (ml)	Concentration (mg/ml)
IV[1]	1g	9.6	100
Reconstitution of Ceftriaxone with Lidocaine Injection BP 1%, 5ml			
	Vial/Bottle dosage	Amount of diluent	Resultant
	Size	to add (ml)	Concentration (mg/ml)
IM[1]	1g	5.0	200

1. If required, use more dilute solutions. Inject well within the body of a large muscle.
2. Administered by intermittent infusion. Concentrations between 10 and 40 mg/ml are recommended; however, lower concentrations may be used.

Admixture compatibility : Do not physically mix with other antimicrobial drugs because of possible incompatibility.

STORAGE:

Protect from heat and light.
Store in a cool and dry place.
KEEP OUT OF THE REACH OF CHILDREN.

PRESENTATION:

ROCICARE 1 GM is available in a glass vial.

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