1.6.3Patient information leaflet (PIL)

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

CEFTRIMED

CEFTRIAXONE USP 1G INJECTION

Prescription Only Medicine

COMPOSITION:

Each vial contains:
Ceftriaxone sodium (Sterile)
equivalent to ceftriaxone 1 g

PHARMACOLOGICAL CLASSIFICATION:
Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Ceftriaxone is a broad-spectrum cephalosporin with a long plasma elimination half-life of approximately 8 hours in normal adults.
Antimicrobial Profile:
(In vitro sensitivity does not necessarily imply *in vitro* efficacy).
The *in vitro* spectrum of activity of ceftriaxone encompasses:
(a) Gram-positive organisms:
Streptococcus pneumoniae, *Streptococcus* Group A (including *Streptococcus pyogenes), Streptococcus* Group B (including *Streptococcus agalactiae), Streptococcus viridans, Streptococcus bovis* (Group D), *Staphylococcus aureus* (methicillin sensitive). *Peptostreptococcus* sp., and *Clostridium* sp.
Note: Methicillin-resistant *Staphylococcus* spp. are resistant to ceftriaxone. *Enterococcus faecalis, Enterococcus faecium* and *Listeria monocytogenes* are resistant.
(b) Gram-negative organisms:
Haemophilus influenzae (including ampicillin-resistant strains), *Haemophilus parainfluenzae, Neisseria meningitidis, Neisseria gonorrhoeae* (including penicillin-resistant strains),*Escherichia coli, Klebsiella* sp**, *Enterobacter* sp*, *Serratia marcescens*, *Citrobacter* sp., *Proteus mirabilis, Indole-positive Proteus* (including *Morganella morganii*), *Salmonella* sp., *Shigella* sp., *Yersinia pestis* and *Treponema pallidum* (in animal experiments).
*Some isolates of these species are resistant to ceftriaxone, due to the production of the chromosomally encoded beta-lactamases.
**Some isolates of these species are resistant due to production of extended spectrum plasmid mediated beta-lactamase.
(c) Organisms which are only partially sensitive to ceftriaxone *in vitro*. *Staphylococcus epidermidis, Pseudomonas aeruginosa, Acinetobacter* sp. and *Bacteroides* sp. Ceftriaxone is stable in relation to the majority of beta-lactamases.
The following organisms are resistant:
Ureaplasma urealyticum, Mycoplasma sp., Mycobacterium sp., Fungi.
It is essential to note that recommended media (free from inhibitory substances especially thymidine and thymine) and methods must be used for satisfactory sensitivity testing.

PHARMACOKINETICS
Ceftriaxone is not absorbed after oral administration. But it is completetely absorbed following intramuscular (IM) administration with peak levels occurring 2-4 hours after the dose. Certriaxone is reversibility bound to plasma proteins wth 95% at plasma concentrations of less than 25 mcg/ml and 85% at 300mcg/ml. Binding is less in neonates and children. Ceftriaxone penetrates well into most tissues and body fluids including CSF (with inflamed or non-inflamed meninges), sputum, pleural and peritoneal fluids, ascetic fluids, tears, blister fluid, bile, gall bladder wall, bone myometrium, fallopian tubes, prostrate, nasal mucosa, tonsil, middle ear mucosa and synovial fluid. Ceftriaxone is the first systemic cephalosporin to penetrate adequately into vitreous humour. Ceftriaxone is not metabolized in the body. 33 to 67% of the ceftriaxone is excreted unchanged in the urine. The rest is secreted into the bile and ultimately excreted in the faeces as inactive compounds.

SURGICAL PROPHYLAXIS:
The preoperative administration of a single 1 gm dose of ceftriaxone may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or partially contaminated (e.g.-vaginal or abdominal hysterectomy or cholecystectomy for chronic calculus cholecystitis to high risk patients, such as those over 70 years of age with acute cholecystitis not requiring therapeutic antimicrobials, obstructive jaundice or common duct bile stones) and in surgical patients for whom infection at the operative site would present serious risk(e.g. during coronary artery bypass surgery). Although ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery.
When administered prior to surgical procedures for which it is indicated, a single 1 gm dose of ceftriaxone provides protection for most infections due to susceptible organism throughout the course of the procedure.
Before instituting treatment with ceftriaxone, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.

INDICATIONS:
Infections caused by pathogens sensitive to ceftriaxone such as
-Sepsis
- Meningitis in neonates and infants
- Perioperative prophylaxis of infections
- Renal and urinary tract infections
- Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections.
- Infections of the bones, joints, soft tissue, skin and wounds
- Abdominal infections (peritonitis, infections of the biliary tract).
- Uncomplicated gonorrhoea.

CONTRAINDICATIONS
Allergy to cephalosporins, in patients hypersensitive to penicillin, the possibility of allergic cross reactions should be borne in mind.
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.
WARNINGS:
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.
DOSAGE AND DIRECTIONS FOR USE:
Adults: 1-2 g IM or IV daily up to a maximum of 4g/day. Gonorrhea: a single IM dose of 250mg
Children: 50-75 mg/kg/day up to a maximum of 2 g/day. Meningitis: 100 mg/kg/day up to 4 g/day.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
In the case of overdose, plasma concentration would not be reduced by haemodialysis or peritoneal dialysis. Treatment is supportive and symptomatic.
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-methyl-thiotetrazole 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.
There may be antagonism between Ceftriaxone and bacteriostatic antibacterial agents. Ceftriaxone may interfere with the Jaffe method of measuring creatinine concentrations and may produce falsely high values; this should be borne in mind when measuring renal function.
In patients treated with ceftriaxone the Coombs'test may become false positive. Ceftriaxone may result in false positive tests for galactosemia.
Likewise, non-enzymatic 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.

RECONSTITUTION INSTRUCTION
Reconstitute with 9.6ml of Water for Injection BP for IV use.
Reconstitute with 3.6ml of Water for Injection BP for IM use.
PRESENTATION
Ceftriaxone 1g: Box containing 1 clear glass vial.
Ceftriaxone 1g: Box containing 10 clear glass vials.
STORAGE INSTRUCTIONS
Store in a dry place below 30°C. Protect from light.
KEEP MEDICINES OUT OF REACH OF CHILDREN.

Mfg. By:

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