Cefuroxime is bactericidal and has a similar spectrum of antimicrobial action and pattern of resistance to those of cefamandole. It is more resistant to hydrolysis by beta-lactamases than cefamandole, and therefore may be more active against beta-lactamaseproducing strains of, for example, *Haemophilus influenza* and *Neisseria gonorrhoeae*. However, treatment failures have occurred in patients with *H. influenza* meningitis given cefuroxime and might be associated with a relatively high minimum bactericidal concentration when compared with the minimum inhibitory concentration or with a significant inoculum effect. Reduced affinity of penicillin-binding proteins for cefuroxime has also been reported to be responsible for resistance in a beta-lactamase-negative strain of *H. influenzae*.

USES AND ADMINISTRATION

Cefuroxime is a second-generation cephalosporin antibacterial used in the treatment of susceptible infections. These have included bone and joint infections, bronchitis (and other lower respiratory-tract infections), gonorrhoea, meningitis (although treatment failures have been reported in *H. influenzae* meningitis), otitis media, peritonitis, pharyngitis, sinusitis, skin infections (including soft-tissue infections), and urinarytract infections. It is also used for surgical infection prophylaxis. For details of these infections and their treatment, see under Choice of Antibacterial. *Administration and dosage.* Cefuroxime is given orally as the acetoxyethyl ester, cefuroxime axetil, in the form of tablets or suspension with or after food, or by injection as the sodium salt. Cefuroxime sodium may be given by deep intramuscular injection, by slow intravenous injection over 3 to 5 minutes, or by intravenous infusion. Doses of cefuroxime axetil and cefuroxime sodium are expressed in terms of the equivalent amount of cefuroxime; 1.20 g of cefuroxime axetil and 1.05 g of cefuroxime sodium are each equivalent to about 1 g of cefuroxime.

Usual oral doses for adults are 125 mg twice daily for uncomplicated urinary-tract infections and 250 to 500 mg twice daily for respiratory-tract infections. A dose for children more than 3 months of age is 125 mg twice daily or 10 mg/kg twice daily to a maximum of 250 mg daily. Children over 2 years of age with otitis media may be given 250 mg twice daily or 15 mg/kg twice daily to a maximum of 500 mg daily.

By injection the usual adult dose is 750 mg of cefuroxime every 8 hours but in more severe infections 1.5 g may be given intravenously every 8, or in some cases every 6, hours. Infants and children can be given 30 to 60 mg/kg daily, increased to 100 mg/kg daily if necessary, given in 3 or 4 divided doses. Neonates may be given similar total daily doses but in 2 or 3 divided doses. Adults with pneumonia or with acute exacerbations of chronic bronchitis may respond to sequential therapy with parenteral cefuroxime 1.5 g twice daily or 750 mg twice daily respectively, followed by oral cefuroxime 500 mg twice daily in each case. For Lyme disease in adults, an oral dose of 500 mg is given twice daily for 20 days.

For details of reduced dosage of cefuroxime in patients with renal impairment, see below.

For the treatment of meningitis due to sensitive strains of bacteria, cefuroxime is given intravenously in adult doses of 3 g every 8 hours. Infants and children are given 200 to 240 mg/kg daily intravenously in 3 or 4 divided doses, which may be decreased to 100 mg/kg daily after 3 days or when there is clinical improvement.

For neonates, a dose of 100 mg/kg daily, decreased to 50 mg/kg daily when indicated, may be used.

In the treatment of gonorrhoea, a single dose of 1.5 g by intramuscular injection, divided between 2 injection sites, has been used. A single 1-g oral dose of cefuroxime has been given for uncomplicated gonorrhoea. In each case an oral dose of probenecid 1 g may be given with cefuroxime. For surgical infection prophylaxis, the usual dose is 1.5 g of cefuroxime intravenously before the procedure; this may be supplemented by 750 mg intramuscularly every 8 hours for up to 24 to 48 hours depending upon the procedure. For total joint replacement, 1.5 g of cefuroxime powder may be mixed with the methylmethacrylate cement.

ADMINISTRATION IN RENAL IMPAIRMENT.

Parenteral doses of cefuroxime may need to be reduced in renal impairment. Licensed product information suggests the following doses based on creatinine clearance (CC):

CC 10 to 20 mL/minute: 750 mg twice daily

CC less than 10 mL/minute: 750 mg once daily

Patients undergoing haemodialysis should receive an additional 750-mg dose following each dialysis; those undergoing continuous peritoneal dialysis may be given 750 mg twice daily.

KIDNEY:

Elevations in serum creatinine and/or blood urea nitrogen and a decreased creatinine clearance have been observed, but their relationship to cefuroxime is unknown.

ADVERSE REACTIONS:

Vomiting, abdominal pain, colitis, vaginitis including vaginal candidiasis, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage.

Several cephalosporins, including Cefuroxime for Injection, have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy should occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

Storage: - Store in cool dry and dark place protect from light & moisture temperature not exceeding 30° C.

Improper Storage may be Deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: - Each pack contain 750 mg of Cefuroxime for Injection IP in a vial. And Sterile Water for Injection IP

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
At. Vill. Surajpur Nahan Road Paonta Sahib, Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in

For the use only of a Registered Medical Practitioner or a hospital or a laboratory

℞Cefuroxime for Injection IP

AMERICAN
FUXORIME **750mg**
Injection

FOR IM/IV USE

Composition:-

Each Vial Contains:-

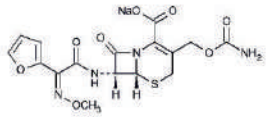
Cefuroxime Sodium (Sterile) IP

Eq. to Cefuroxime 750 mg

DESCRIPTION

Cefuroxime is a semisynthetic, broad-spectrum, cephalosporin antibiotic for parenteral administration. It is the sodium salt of (7R)-3-carbamoyloxymediy1-7-[(Z) - furan-2-y1-2-methoxyiminoacetamido]-3-cephem-4-carboxylate.

And it has the following chemical structure: The empirical formula is $C_{16}H_{15}N_4NaO_8S$, representing a molecular weight of 446.4.



Cefuroxime Sodium

CLINICAL PHARMACOLOGY

After intramuscular (IM) injection of a 750-mg dose of cefuroxime to normal volunteers, the mean peak serum concentration was 27 mcg/mL. The peak occurred at approximately 45 minutes (range, 15 to 60 minutes). Following IV doses of 750 mg and 1.5 grams, serum concentrations were approximately 50 and 100 mcg/mL, respectively, at 15 minutes. Therapeutic serum concentrations of approximately 2 mcg/mL or more were maintained for 5.3 hours and 8 hours or more, respectively. There was no evidence of accumulation of cefuroxime in the serum following IV administration of 1.5-g doses every 8 hours to normal volunteers. The serum half-life after either IM or IV injections is approximately 80 minutes.

Approximately 89% of a dose of cefuroxime is excreted by the kidneys over an 8-hour period, resulting in high urinary concentrations.

Following the IM administration of a 750-mg single dose, urinary concentrations averaged 1,300 mcg/mL during the first 8 hours. Intravenous doses of 750 mg and 1.5 g produced urinary levels averaging 1,150 and 2,500 mcg/mL, respectively, during the first 8-hour period.

The concomitant oral administration of probenecid with cefuroxime slows tubular secretion, decreases renal clearance by approximately 40%, increases the peak serum level by approximately 30%, and increases the serum half-life by approximately 30%. Cefuroxime is detectable in therapeutic concentrations in pleural fluid, joint fluid, bile, sputum, bone, and aqueous humour.

Cefuroxime is detectable in therapeutic concentrations in cerebrospinal fluid (CSF) of adults and paediatric patients with meningitis. The following table shows the concentrations of cefuroxime achieved in cerebrospinal fluid during multiple dosing of patients with meningitis.

PHARMACOLOGY

PHARMACOKINETICS

Cefuroxime is absorbed from the gastrointestinal tract and is rapidly hydrolysed in the intestinal mucosa and blood to cefuroxime; absorption is enhanced in the presence of food. Peak plasma concentrations are reported about 2 to 3 hours after an oral dose. The sodium salt is given by intramuscular or intravenous injection. Peak plasma concentrations of about 27 micrograms/mL have been achieved 45 minutes after an intramuscular dose of 750 mg with measurable amounts present 8 hours after a dose. Up to 50% of cefuroxime in the circulation is bound to plasma proteins. The plasma half-life is about 70 minutes and is pro-longed in patients with renal impairment and in neonates. Cefuroxime is widely distributed in the body including pleural fluid, sputum, bone, synovial fluid, and aqueous humour, but only achieves therapeutic concentrations in the CSF when the meninges are inflamed. It crosses the placenta and has been detected in breast milk.

Cefuroxime is excreted unchanged, by glomerular filtration and renal tubular secretion, and high concentrations are achieved in the urine. On injection, most of a dose of cefuroxime is excreted within 24 hours, the majority within 6 hours. Probenecid competes for renal tubular secretion with cefuroxime resulting in higher and more prolonged plasma concentrations of cefuroxime. Small amounts of cefuroxime are excreted in bile. Plasma concentrations are reduced by dialysis.

ADVERSE EFFECTS AND PRECAUTIONS

Gastrointestinal disturbances, including diarrhoea, nausea, and vomiting, have occurred in some patients receiving cefuroxime axetil. There have been rare reports of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. Mild to moderate hearing loss has been reported in some children given cefuroxime for the treatment of meningitis.

ANTIMICROBIAL ACTION