Only for the use of medical professionals

Furocef®

cefuroxime

PRESENTATION

Furocef® 125mg tablets : Each film coated tablet contains 125 mg of cefuroxime (as cefuroxime axetil USP). **Furocef® 250mg tablets :** Each film coated tablet contains 250mg of cefuroxime (as cefuroxime axetil USP). **Furocef® 500mg tablets :** Each film coated tablet contains 500mg of cefuroxime (as cefuroxime axetil USP). **Furocef® powder for oral suspension :** Provided as dry, white to pale yellow powder. When reconstituted as directed, each 5 ml of suspension provides the equivalent of 125 mg of cefuroxime (as cefuroxime axetil USP), **Furocef® 250mg IV/IM Injection :** Each vial contains 250mg of cefuroxime (as cefuroxime sodium USP). **Furocef® 750mg IV/IM Injection :** Each vial contains 750mg of cefuroxime (as cefuroxime sodium USP). **Furocef® 1gm IV/IM :** Each vial contains 1g of cefuroxime (as cefuroxime sodium USP). **Furocef® 1.5gm IV :** Each vial contains 1.5g of cefuroxime (as cefuroxime sodium USP).

CLINICAL PHARMACOLOGY

Mode of Action : The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

Microbiology : The drug has broad-spectrum antibacterial activity and is highly stable to bacterial beta-lactamases, especially plasmid-mediated enzymes that are commonly found in the Enterobacteriaceae. It is active against gram-positive and gram-negative cocci, gram negative bacilli, and anaerobes. Cefuroxime has been demonstrated to be active against most strains of the following microorganisms: ***Aerobic gram-positive microorganisms:*** *Staphylococcus aureus* (including beta-lactamase-*producing strains*). *Streptococcus pneumoniae, Streptococcus pyogenes.* ***Aerobic gram-negative microorganisms:*** *Escherichia coli, Haemophilus influenzae (including beta-lactamase-producing strains), Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis* (including beta- lactamase-producing strains), *Neisseria gonorrhoeae* (including beta-lactamase-producing strains), Spirochetes: *Borrelia burgdorferi.*

Pharmacokinetics : After oral administration. cefuroxime axetil is absorbed from the gastrointestinal tract and rapidly hydrolysed by nonspecific esterases in the intestinal mucosa and blood to cefuroxime. Cefuroxime is subsequently distributed throughout the extracellular fluids. the axetil moiety is metabolised to acetaldehyde and acetic acid. It is approx 50% protein bound, the half-life is 1.2 hr. Absorption is greater when taken after food. The drug is excreted unchanged in the urine; in adults, approx. 50% of the administered dose is recovered in the urine within 12 hours. Because cefuroxime is renally excreted. the serum half-life is prolonged in patients with reduced renal function. Despite the lower elimination of cefuroxime in geriatric patients, dosage adjustment based on age is not necessary.

INDICATIONS

Furocef® is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed bleow:

- ***Pharyngitis/tonsillitis*** caused by *Streptococcus pyogenes*
- ***Acute bacterial otitis media*** caused by *S. pneumoniae, H. influenzae* (including beta lactamase-producing strains), *M. catarrhalis* (including beta-lactamase-producing strains) or *S. pyogenes.*
- ***Acute bacterial maxillary sinusitis*** caused by *S. pneumoniae, or H. influenzae* (nonbeta-lactamase-producing strains only)
- ***Acute becterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis*** caused by *S. penumoniae, H. influenzae* (beta-lactamase negative strains), or *H. parainfluenzae* (beta-lactamase negative strains)
- ***Uncomplicated skin and skin-structure infections*** caused by *S. aureus* (including beta-lactamase-producing strains), or *S. pyogenes*
- ***Uncomplicated urinary tract infections*** caused by *E. coli* or *K. pneumoniae*
- ***Uncomplicated gonorrhoea, urethral and endocervical infections*** caused by penicillinase-producing and non-penicillinase-producing strains of N. gonorrhoeae and **uncomplicated rectal** gonorrhoea in females causd by non-penicillinase-producing strains of *N.gonorrhoeae*
- ***Early Lyme disease (erythema migrans)*** caused *by Borrelia burgdorferi.*
- ***Bone and joint infection*** for example, osteomyelitis and septic arthritis.
- ***Obstetric and gynaecological infection,*** pelvic inflammatory diseases.
- ***Other infections*** including septicemia and meningitis.
- ***Prophylaxis against infections*** in abdominal, pelvic, orthopedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.

DOSAGE AND ADMINISTRATION

Oral : Furocef® should be taken after food for optimum absorption.

Population	Infection	Dosage	Duration (days)
Adolescents and Adults (13 years and older)	Pharyngitis/tonsillitis	250 mg bid	10
	Acute bacterial maxillary sinusitis	250 mg bid	10
	Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg bid	10
	Secondary bacterial infections of acute bronchitis	250 or 500 mg bid	5-10
	Uncomplicated skin and skin-structure infections	250 or 500 mg bid	10
	Uncomplicated urinary tract infections	125 or 250 mg bid	7-10
	Uncomplicated gonorrhea	1000 mg once	single dose
	Early Lyme disease	500 mg bid	20
Pediatric (who can swallow tablet)	Pharyngitis/tonsillitis	125 mg bid	10
	Acute otitis media	250 mg bid	10
	Acute bacterial maxillary sinusitis	250 mg bid	10

Dry Powder for Suspension: Usual dose : 10-15 mg/kg bid

Infection	Dosage	Duration (days)
Pharyngitis/tonsillitis	10mg/kg bid	10
Acute otitis media	15mg/kg bid	10
Acute bacterial maxillary sinusitis	15mg/kg bid	10
Impetigo and other skin infections	15mg/kg bid	10

Parenteral:

General Dosage Recommendation

Adult and Adolescent : Many infections will respond to 750 mg t.d.s by IM or IV injection. For more severe infections, this dose should be increased to 1.5g t.d.s IV. The frequency of IM or IV injections can be increased to six-hourly if necessary, giving total Doses of 3g to 6g daily

Neonates: 10 to 33.3 mg/kg body weight t.d.s by IM or IV injection or 15 to 50 mg/kg body weight b.i.d

Infants & Children : 16.7 to 33.3 mg/kg of body weight t.d.s. A dose of 60mg/kg/day will be appropriate for most infections.

Other recommendations:

Meningitis : **Furocef®** is suitable for sole therapy of bacterial meningitis due to sensitive strains. The following dosage are recommended.

Adults : upto 3g IV t.d.s

Neonates : 33.3 mg/kg of body weight t.d.s or 50 mg/kg of body weight b.i.d (the initial dosage should be 100 mg/kg/day IV.A reduction to 50mg/kg/day IV may be made when clinically indicated

Infants & Children : 50 to 60 mg/kg of body weight every six hours. or 66.7 to 80 mg/kg of body weight t.d.s. This dosage may be reduced to100mg/kg/day IV after 3 days or when clinical improvement occurs

Gonorrhea

Adult : 1.5g IM should be given as single dose.1.5g should be divided into two doses (2x750mg) and administered two separate sites, e.g each buttock

Children : Gonorrrhea in children has been treated successfully with a single IM dose of cefuroxime,25mg/kg body weight.

Bone and joint infections

Adults : 1.5g IV t.d.s

Children above 3 months :150mg/kg/day (not to exceed the maximum adult dosage) in equally divided doses every 8 hours

Surgical Prophylaxis

Clean-contaminated or potentially contaminated surgical procedure : 1.5gm IV before 1/2-1hr before the initial incision. Thereafter 750mg IV or IM/8 hours when the procedure is prolonged.

Open heart surgery : 1.5gm IV at the induction of anesthesia & every 12 hours thereafter for a total of 6 gms is recommended.

Elderly & renally impaired patients: No dosage adjustment is necessary based on age.

In renal impairment, dose may be reduced (for parenteral administration only) when creatinine clearance falls below 20 ml/min. In aadults with marked renal impairment(creatinine clearance 10-20 ml/min). 750 mg b.i.d is recommended and with severe impairment (creatinine clearance<10 ml/min),750 mg once daily is adequate. For patients on dialysis a further 750 mg dose should be given at the end of each dialysis. When continuous peritoneal dialysis is being used, a suitable dosage is usually 750 mg b.i.d.

DIRECTION FOR RECONSTITUTION : Suspension: Tap bottle until all powder flows freely. Add 30 ml of boiled and cooled water with the provided measuring cup and shake vigorously to obtain suspension. **Shake vigorously before use**.

Injection: IM: Add 1 ml WFI to 250 mg /3 ml WFI to 750 mg and 4mL WFI to 1g Furocef powder and shake gently to produce an opaque suspension. ***IV:*** Dissolve 250 mg powder in at least 2 ml WFI, 750 mg powder in at least 8 ml WFI, 1g powder to at least 11mL and 1.5gm powder in at least 16 ml WFI. **For IV infusion (up to 30 minutes),** 1.5gm may be dissolved in 50ml WFI or commonly used IV infusion fluids (e.g. 0.9% sodium Chloride injection, 5% Dextrose injection, 10% Dextrose injection, 5% Dextrose and 0.9% Sodium Chloride Injection, 5% Dextrose and 0.45% Sodium Chloride Injection; or 1/6 M Sodium Lactate Injection)

This solution may be given directly into the vein or introduced into the tubing of giving set if the patient is receiving parenteral fluids.

For intermittent IV Infusion with a Y-type administration set, dosing can be accomplished through the tubing system by which the patient may be receiving other IV solutions. However, during infusion of the solution containing Furocef it is advisable to temporarily discontinue administration of any other solutions at the same site.

For Continuous IV Infusion. a solution of Furocef may be added to an IV Infusion pack containing commonly used IV infusion fluid.

SIDE EFFECTS

General : Anaphylaxis, angioedema, pruritus, rash, serum sickness-like reaction and urticaria. Gastrointestinal: Pseudomembranous colitis. Hematological: Haemolytic anaemia, leukopenia, pancytopenia, thrombocytopenia and increased prothrombin time. Hepatic: Hepatic impairment including hepatitis and cholestasis, jaundice. Neurological: Seizure. Skin: Erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. Urological: Renal dysfunction. Cephalosporin-class adverese reactions: Toxic nephropathy, aplastic anaemia, haemorrhage, increased BUN, increased creatinine, false-positive test for urinary glucose, increased alkaline phosphatase, neutropenia, elevated bilirubin and agranulocytosis.

CONTRAINDICATIONS

Contraindicated in patients with known hypersensitivity to the cephalosporin group of antibiotics.

PRECAUTIONS

As with other broad-spectrum antibiotics, prolonged administration of cefuroxime may result in overgrowth of nonsusceptible microorganisms and also should be prescribed with caution in individuals with a history of pseudomembranous colitis. The safety and effectiveness of cefuroxime axetil have not been established in patients with gastrointestinal malabsorption. If superinfection occurs during therapy, appropriate measures should be taken. Cefuroxime should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function. Prothrombin time should be monitored in patients at risk.

Pregnancy & Lactation: Because cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with cefuroxime.

OVERDOSAGE

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

DRUG INTERACTIONS

Probenecid increases cefuroxime blood levels; drugs lowering gastric acidity may decrease cefuroxime bioavailability.

PACKAGE QUANTITIES

Furocef® 125mg tablets: Box containing 2x5 film coated tablets in blister pack.
Furocef® 250mg tablets: Box containing 2x8 film coated tablets in blister pack.
Furocef® 500mg tablets: Box containing 2x6 film coated tablets in blister pack.
Furocef® powder for oral suspension: Bottle containing 70 ml of suspension after reconstitution.
Furocef® 250mg IV/ IM Injection: Pack containing 1 vial with 1 ampoule of Water for Injection.
Furocef® 750mg IV/ IM Injection: Pack containing 1 vial with 1 ampoule of Water for Injection.
Furocef® 1g IV/ IM Injection: Pack containing 1 vial with 2 ampoule of Water for Injection.
Furocef® 1.5 gm IV for : Pack containing 1 vial with 2 ampoule of water for Injection

STORAGE

Tablets & Injections/Infusions : Store between 15-30^{0}C. When constituted as directed with sterile water for injection, suspensions or solution of **Furocef®** IM/IV injection maintain satisfactory potency for 24 hours at room tepmerature and 48 hours under refrigeration (5^{0}C). Infusion suspensions remain stable for 24 hours below 25^{0}C and 72 hours if refrigerated. It will retain potency for up to 24 hours at room temp, in sodium chloride injection BP 0.9%, dextrose injection BP 0.18%, sodium chloride plus 4% dextrose injection BP and compound sodium lactate injection BP (Hartmann's solution). **Furocef®** is also compatible with aqueous solutions containing up to 1% lignocaine HCl. **Dry powder for Suspension:** Before reconstitution, store dry powder for suspension between 2-30^{0}C. After reconstitution, store suspension between 2-25^{0}C in a refrigerator or at room temperature. Shake well before use. Discard after 10 days of reconstitution.

Manufactured By
Renata Limited
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