Fosfocin

90 mm X 200 mm

Only for the use of Medical Professionals

Fosfocin®

Fosfomycin Trometamol

Description

Fosfocin® is the preparation of Fosfomycin Trometamol which has in *vitro* activity against a broad range of gram positive and gram negative aerobic microorganisms, associated with uncomplicated urinary tract infections. Fosfomycin is bactericidal in urine at therapeutic doses. The bactericidal action of Fosfomycin is due to its inactivation of the enzyme enolpyruvyl transferase, thereby irreversibly blocking the condensation of uridine diphosphate-N-acetylglucosamine with p-enolpyruvate, one of the first steps in bacterial cell wall synthesis. It also reduces adherence of bacteria to uroepithelial cells.

Indications

Fosfocin® is indicated in the treatment of acute uncomplicated lower urinary tract infections (acute cystitis) in women 18 years of age and older caused by the following susceptible pathogens of *Escherichia coli, Enterococcus faecalis*.

Dosage and administration

The recommended dosage for women 18 years of age and older for uncomplicated lower urinary tract infections (acute cystitis) is one sachet of **Fosfocin®** with or without food (Single dose only). Safety and effectiveness have not been established in children under 18 years of age.

Instruction for use

Fosfocin® should be taken orally. At first pour the diluent in a glass, then add full contents of one **Fosfocin®** sachet into diluent and stir to dissolve completely. Drink full mixture immediately after preparation.

Fosfocin® should not be taken in its dry form.

Use in pregnancy and lactation

Pregnancy: Fosfomycin is pregnancy category B. There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Lactation: It is not known whether fosfomycin is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from fosfomycin, a decision should be made whether to discontinue nursing or not to administer the drug, taking into account the importance of the drug to the mother.

Side effects

The side effects of fosfomycin are diarrhea, nausea, vaginitis, dizziness, headache, asthenia and dyspepsia.

Contraindications

Fosfomycin is contraindicated in patients with known hypersensitivity to fosfomycin or any of the components of this preparation. Fosfomycin is not indicated for the treatment of pyelonephritis or perinephric abscess.

Warnings and precautions

Warnings: *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including fosfomycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Precautions: Do not use more than one single dose of fosfomycin to treat a single episode of acute cystitis. Repeated daily doses of fosfomycin did not improve the clinical success or microbiological eradication rates compared to single dose therapy, but did increase the incidence of adverse events. Urine specimens for culture and susceptibility testing should be obtained before and after completion of therapy. If the symptoms are not improve in two to three days after taking fosfomycin, the patient should contact with the physician.

Drug interactions

When fosfomycin is co-administered with metoclopramide (a drug which increases gastrointestinal motility), it will lower the serum concentration and urinary excretion of fosfomycin. Other drugs that increase gastrointestinal motility may produce similar effects.

Overdose

In acute toxicology studies, oral administration of high doses of fosfomycin up to 5 g/kg were well tolerated in mice and rats, produced transient and minor incidences of watery stool in rabbits, and produced diarrhea with anorexia in dogs occurring 2 to 3 days after single dose administration. These doses represent 50 to 125 times the human therapeutic dose. The following events have been observed in patients who have taken fosfomycin in overdose: vestibular loss, impaired hearing, metallic taste, and general decline in taste perception. In the event of overdosage, treatment should be symptomatic and supportive.

Pharmaceutical precautions

Keep away from the reach of children. Store in a cool (below 25°C) and dry place protected from light.

Presentation

Fosfocin® powder: Each sachet contains Fosfomycin Trometamol BP equivalent to Fosfomycin 3g.

Package quantities

Fosfocin® powder: Carton of 1 Alu-Alu sachet with diluent.

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