

Fosamin® 3 g

Fosfomycin
Granules for Oral Solution

Description

Fosfomycin Trometamol is a phosphonic acid derivative. It is a synthetic, broad spectrum, bactericidal antibiotic for oral administration.

Indications

It is indicated only for the treatment of acute cystitis (uncomplicated urinary tract infection) in women due to susceptible strains of *Escherichia coli* and *Enterococcus faecalis*.

Dosage and Administration

The recommended dosage for women 18 years of age and older for acute cystitis is one sachet of Fosfomycin with or without food. This medicine should not be used in children.

Contraindications

Fosfomycin is contraindicated in patients with known hypersensitivity to the drug and patients with severe renal insufficiency and patients undergoing haemodialysis.

Precautions

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Fosfomycin. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

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.

Adverse Effects

In clinical trials, the most frequently reported adverse events occurring in > 1% of the study population regardless of drug relationship were: diarrhea 10.4%, headache 10.3%, vaginitis 7.6%, nausea 5.2%, rhinitis 4.5%, back pain 3.0%, dysmenorrhea 2.6%, pharyngitis 2.5%, dizziness 2.3%, abdominal pain 2.2%, pain 2.2%, dyspepsia 1.8%, asthenia 1.7%, and rash 1.4%. The following adverse events occurred in clinical trials at a rate of less than 1%, regardless of drug relationship: abnormal stools, anorexia, constipation, dry mouth, dysuria, ear disorder, fever, flatulence, flu syndrome, hematuria, infection, insomnia, lymphadenopathy, menstrual disorder, migraine, myalgia, nervousness, paresthesia, pruritus, SGPT increased, skin disorder, somnolence, and vomiting. One patient developed unilateral optic neuritis, an event considered possibly related to Fosfomycin therapy.

Use in Pregnancy & Lactation

Pregnancy category: B

This drug should not be used during pregnancy unless the benefit outweighs the risk.

A decision should be made to discontinue breastfeeding or to not administer the drug, taking into account the importance of the drug to the mother.

Drug Interactions

Metoclopramide: When coadministered with Fosfomycin, metoclopramide, a drug which increases gastrointestinal motility, lowers the serum concentration and urinary excretion of Fosfomycin. Other drugs that increase gastrointestinal motility may produce similar effects.

Cimetidine: Cimetidine does not affect the pharmacokinetics of Fosfomycin when coadministered with Fosfomycin.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Fosamin® 3 g Granules for Oral Solution: Box containing 1 sachet of granules for oral solution. Each sachet contains Fosfomycin Trometamol BP equivalent to 3 g Fosfomycin.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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