Fosfomax™

Fosfomycin 3 gm

COMPOSITION
Each sachet contains Fosfomycin Trometamol EP granules for oral solution equivalent to 3 gm Fosfomycin.

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

INDICATION
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*.

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

PREPARATION
Pour the entire content of the **Fosfomax**™ sachet into 100 ml of water then stir gently to dissolve. Hot water should not be used. **Fosfomax**™ should be taken immediately after dissolving in water.

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

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.

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.

USE IN PREGNANCY AND 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 INTERACTION
Metoclopramide: When co-administered 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.

PHARMACEUTICAL PRECAUTIONS
Keep out of the reach of children. Store in a cool & dry place below 25^{0} C. protected from light.

HOW SUPPLIED
Fosfomax™ : Box containing 1 sachet of Fosfomycin Trometamol EP granules for oral solution equivalent to 3 gm Fosfomycin.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH