Fosmol

Fosfomycin Trometamol

3 g
Sachet

فوسمول ساشے

COMPOSITION:
Each sachet contains:
Fosfomycin (as Trometamol) ..... 3 g.

Product Specs.: Innovator

DESCRIPTION:
FOSMOL contains Fosfomycin trometamol, powder for Oral Solution. It is a synthetic, broad spectrum, bactericidal antibiotic for oral administration. It is available as a single-dose sachet.

INDICATIONS:
Fosfomycin is indicated for the treatment of acute uncomplicated lower urinary tract infections in adults caused by susceptible strains of Escherichia Coli & Enterococcus faecalis.
Fosfomycin is indicated for periprocedural prophylaxis in diagnostic and surgical transurethral procedures.
If persistence or reappearance of bacteriuria occurs after treatment with fosfomycin, other therapeutic agents should be selected.

MECHANISM OF ACTION:
Fosfomycin is indicated for the treatment of acute uncomplicated lower urinary tract infections in adults caused by susceptible strains of Escherichia Coli & Enterococcus faecalis.

MICROBIOLOGY:
Fosfomycin has in vitro activity against a broad range of gram-positive and gram-negative aerobic micro-organisms which are 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 trans¬ferase, 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. There is generally no cross-resistance between fosfomycin and other classes of antibacterial agents such as beta-lactams and aminoglycosides. ***Fosfomycin has been shown to be active against most strains of the following microorganisms:***
Enterococcus faecalis.
Escherichia colt.

DOSAGE &ADMINISTRATION:
Adults:
Uncomplicated lower urinary tract infections: One sachet (3g).
Perioperative prophylaxis of urinary tract infections: One 3g sachet 3 hours before the procedure.
Pediatric population:
Fosfomycin trometamol in a dose of 3g is not suitable for children under the age of 12 years.
Method of administration:
Fosfomycin is for oral administration and should be taken on an empty stomach, either 1 hour before or at least 2 hours after meals and preferably before bedtime after emptying the bladder. The contents of a sachet should be dissolved in a glass of water and taken immediately after its preparation.

PHARMACOKINETICS:
Fosfomycin trometamol is rapidly absorbed following oral administration and converted to the free acid, fosfomycin. Absolute oral bioavailability under fasting conditions is 37%.
The mean apparent steady-state volume of distribution (V_{ss}) is 136.1 (±44.1) L following oral administration. Fosfomycin is not bound to plasma proteins. Fosfomycin is distributed to the kidneys and bladder wall. Fosfomycin has been shown to cross the placental barrier in animals and man. Fosfomycin is excreted unchanged in both urine and feces. Food delays and reduces absorption of fosfomycin trometamol, resulting in reduced blood and urinary concentrations. However, it is unlikely that the efficacy in urinary tract infection would be seriously affected.

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. C. difficile produces toxins A and B which contribute to the development of CDAD.
Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. 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:
Fosfomycin trometamol is principally excreted by the kidney. Caution should be exercised in administering this antibiotic to patients with impaired renal function.
Antibiotic associated colitis (incl. pseudomembranous colitis) has been reported in association with the use of broad spectrum antibiotics including fosfomycin trometamol; therefore it is important to consider this diagnosis in patients who develop serious diarrhea during or after the use of fosfomycin trometamol. In this situation adequate therapeutic measures should be initiated immediately. Drugs inhibiting peristalsis are contraindicated in this situation.
This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
Pregnancy:
There are limited data from the use of fosfomycin in pregnant women. Animal studies with fosfomycin trometamol have shown no hazard to the fetus. Fosfomycin should only be used in pregnancy when the expected benefits outweigh the risk.
Breast-feeding:
Fosfomycin is excreted in breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Fosfomycin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

DRUG INTERACTIONS:
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.

SIDE EFFECTS:
Immune system disorders:
Anaphylactic shock, allergic reactions.
Nervous system disorder.
Headache, dizziness, paraesthesia.
Cardiac & vascular disorders:
Tachycardia, hypotension.
Respiratory, thoracic and mediastinal disorders:
Asthma.
Gastrointestinal disorders:
Dyspepsia, diarrhea, nausea, vomiting, abdominal pain.
Skin and subcutaneous tissue disorders:
Rash, urticaria, pruritus, itching, angioedema.
Reproductive system and breast disorders:
Vulvovaginitis.
General disorders and administration site conditions:
Fatigue.

CONTRAINDICATIONS:
- Hypersensitivity to the active substance or to any of the excipients.
- Patients with severe renal insufficiency
- (CLcr<10ml/min).
- Patients undergoing hemodialysis.

INSTRUCTIONS:
– Store between 15-25°C.
– Protect from heat, sunlight & moisture.
– Keep out of the reach of children.
– Take this sachet on an empty stomach (2-3 hours before or 2-3 hours after a meal), preferably before going to bed after emptying the bladder.
– To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Fosmol 3g : Pack of 1 sachet.

دوا بنانے کا طریقہ:
ساشے میں موجود پاؤڈر کو ایک گلاس پانی میں
حل کریں اور فوراً استعمال کریں۔

ہدایات:
۱۵۔۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
یہ ساشے خالی معدے پر لیں (کھانے سے 2-3 گھنٹے قبل یا 2-3 گھنٹے بعد)،
عام طور پر رات کو سونے سے پہلے اور مثانہ خالی کرنے کے بعد لینا بہتر ہے۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Manufactured by:
PHARMASOL
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FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
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