Prescribing Information

Monuril 3g granules for oral solution

Consult Summary of Product Characteristics before prescribing.

Legal Category: POM
Marketing Authorisation number and basic NHS cost: PL 31654/0006, £4.86 per sachet.
Presentation: One sachet contains 5.631 g of fosfomycin trometamol equivalent to 3.0 g fosfomycin
Uses: Monuril is indicated for:
- the treatment of acute, uncomplicated cystitis in women and female adolescents
- perioperative antibiotic prophylaxis for transrectal prostate biopsy in adult man

Dosage and administration:
Acute, uncomplicated cystitis in women and female adolescents (>12 years of age): 3 g fosfomycin once
Perioperative antibiotic prophylaxis for transrectal prostate biopsy: 3 g fosfomycin 3 hours prior to the procedure and 3 g fosfomycin 24 hours after the procedure.
Method of administration
For oral use. For the indication of acute, uncomplicated cystitis in women and female adolescents it should be taken on an empty stomach (about 2-3 hours before or 2-3 hours after a meal), preferably before bedtime and after emptying the bladder. The dose should be dissolved into a glass of water and taken immediately after its preparation.
Special populations:
Children: The safety and efficacy of Monuril in children below 12 years of age have not been established. Therefore, this medicine should not be used in this age group.
Renal impairment: In patients with impaired renal function, the elimination half-life is increased proportionally to the degree of renal insufficiency. Urinary concentrations of fosfomycin in patients with impaired renal function remain effective for 48 hours after a usual dose if creatinine clearance is above 10 ml/min. In older people fosfomycin clearance is reduced in line with the age related reduction in renal function. Use of Monuril is not recommended in patients with renal impairment (creatinine clearance < 10 ml/min).
Pregnancy: Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Monuril should only be used during pregnancy, if clearly necessary.
Breastfeeding: Fosfomycin is excreted in human milk in low quantities. If clearly necessary, a single dose of oral fosfomycin can be used during breast-feeding.
Warnings and Precautions:
Serious and occasionally fatal hypersensitivity reactions, including anaphylaxis and anaphylactic shock, may occur. Clostridioides difficile-associated colitis and pseudo-membranous colitis have been reported with fosfomycin. It is important to consider this diagnosis in patients who present with diarrhoea. It may be symptomatic of Clostridium Difficile.
Monuril contains sucrose; patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not use this medicine. The presence of sulphites may cause severe hypersensitivity reactions and bronchospasm. Its use is not recommended in patients with hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
No specific studies have been performed but patients should be informed that dizziness has been reported. This may influence some patients' ability to drive and use machines.
Contraindications:
Hypersensitivity to the active substance or to any of the excipients.
Interactions:
Concomitant administration of metoclopramide has been shown to lower serum and urinary concentrations of fosfomycin and should be avoided. Other medicinal products that increase gastrointestinal motility may produce similar effects. Food may delay the absorption of fosfomycin, with consequent slight decrease in peak plasma levels and urinary concentrations. It is therefore preferable to take the medicinal product on an empty stomach or about 2-3 hours after meals.
Side Effects:
The most common adverse reactions following the single-dose administration of fosfomycin trometamol involve the gastrointestinal tract, mainly diarrhoea. Other common undesirable effects are vulvovaginitis, headache, dizziness, nausea, dyspepsia and abdominal pain. Anaphylaxis and angioedema have been reported with an unknown frequency. Consult the summary of product characteristics for other side effects.

Further information is available from
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Zambon UK at drugsafetyUK@zambongroup.com