MONUROL

Presentation

Monurol: Sachets containing 3g of fosfomycin (as fosfomycin trometamol)

Uses Monurol is an anti-bacterial agent. Monurol contains fosfomycin trometamol, an orally well absorbed salt of fosfomycin, which is a broad spectrum antibiotic derived from phosphonic acid. It is indicated for the treatment of acute uncomplicated lower urinary tract infections caused by pathogens sensitive to fosfomycin.

Mode of action: The antibiotic activity of Monurol is due to an inhibition of bacterial cell wall synthesis, its particular mechanism of action, the specific inhibition of enol pyruvyltransferase, results in a lack of cross resistance with other classes of antibiotic and the possibility of synergism with other antibiotics.

Microbiology: Monurol has a broad spectrum of anti-bacterial activity against Gram-positive and Gram-negative otganisms, including beta-lactamase producing strains and the pathogens most frequently isolated in urinary tract infections (E.coli, Proteus, Klebsiella, Enterobacter, Staphylococcus.)

Pharmacokinetics: Monurol is rapidly absorbed from the gastrointestinal tract giving peak plasma concentrations after 2 hours. Monurol is eliminated mainly unchanged through the kidneys and this results in very high concentrations in the urine of approximately 3,000mg/litre within 2-4 hours. Therapeutic concentrations are maintained for periods of 36 or more hours from a single dose.

Dosage and administration: Monurol should by taken on an empty stomach one hour before or 2 hours after meals. Ideally Monurol should be taken before bedtime after emptying the bladder. The contents of sachet should be dissolved in a glass of water and taken immediately after preparation.

Adults including elderly up to 75 years:

Urinary tract infections: In uncomplicated lower urinary a single 3g dose of Monurol should be administered.

Elderly patients over 75 years: Renal impairment may result in sub-therapeutic concentrations and Monurol is not recommended in these patients.

Contraindications, warning, etc

Contraindications: Hypersensitivity to the drug. Severe renal insufficiency (creatinine clearance less than 10 ml/min) and patients undergoing haemodialysis.

Precautions: Food delays and reduces the absorption of fosfomycin trometamol resulting in reduced blood and urine concentrations, however it is unlikely that efficacy in urinary tract infections would be seriously affected. In patients with moderately reduced renal function, including the physiological reduction in the elderly, the half-life of fosfomycin trometamol is slightly prolonged but urinary concentrations remain therapeutically adequate. In severe renal insufficiency and patients undergoing haemodialysis, therapeutic concentrations in the urine would not be achieved.

Use in prenancy and lactation: Teratogenic effects
When administered intramuscularly as the sodium salt at a dose of 1 gm to pregnant women, fosfomycin crosses the placental barrier. Monurol crosses the placental barrier of rats. It does not produce teratogenic effects in pregnant rats at dosages as high as 1,000mg/kg/day (approximately 9 and 1.4 times the human dose based on body weight and mg/m squared respectively) When administered to pregnant female rabbits at dosages as high as 1,000mg/kg/day (approximately 9 and 2.7 times the human dose based on body weight and mg/m squared respectively) teratoxicities were observed. However these toxicities were seen maternally toxic doses and were considered to be due to the sensitivity of the rabbit to changes in the microflora resulting to the antibiotic administration. There are, however, 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. Fosfomycin has been shown to cross into breast milk. Monurol should not therefore be given to lactating women except in the case of real need.

Drug interactions: Concommitant administration of metoclopramide has been shown to lower serum and urinary concentration and should be avoided.

Side-effects: Monurol is generally well tolerated. Occasional gastrointestinal disturbances (nausea, diarrhoea, pyrosis) and less frequently skin rash have been reported. These reactions regree spontaneously and rapidly without requiring any particular or specific therapy.

Overdosage: No cases of overdose have been reported. In the event of overdose, it is sufficient to encourage the urinary elimination of the drug through adequate administration of oral fluids.

Pharmaceutical precautions Store at room temperature in the manufacturer's packaging. The granules should be dissolved in water immediately before use.

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