MONUROL

CONTENTS: Fosfomycin trometamol.
PRESENTATION: Sachet 3 g (white or near white crystalline powder) x 1's.
DESCRIPTION: Each sachet contains fosfomycin trometamol 5.631 g equivalent to fosfomycin 3 g.
Fosfomycin trometamol is very soluble in water and has a molecular weight of 182.02.
ACTIONS: Pharmacology: Mechanism of Action: Monurol shows a high bactericidal activity due to the metabolic block of the cell wall synthesis (specific inhibition of the enol pyruvyltransferase enzyme) from which it derives the absence of cross-resistance with the other antibiotics.
Microbiology: Monurol has a high broad-spectrum bactericidal activity against gram-positive and gram-negative microorganisms, including penicillinase-producing strain and the bacteria most frequently isolated in urinary infections (*Escherichia coli*, Proteus, Klebsiella, Enterobacter, Pseudomonas, Staphylococcus> and others).
Pharmacokinetics: Fosfomycin trometamol is rapidly absorbed by the gastrointestinal tract. The absolute bioavailability of fosfomycin of Monurol, calculated from plasma levels and urinary excretion after oral and IV concentrations, ranges from approximately 33-58% with dose of 1.5-3 g. Mean peak plasma concentrations generally occur at 2-3 hrs after dosing. Fosfomycin is not bound to plasma proteins. After oral administration, the drug distributes in all the compartments of the genitourinary tract, with a high and therapeutically effective concentration in the kidney up to 24 hrs after dosing.
No information regarding fosfomycin metabolism are currently available.
Fosfomycin is eliminated mainly through the kidney and this results in very high urinary concentrations. Therapeutic concentrations of the active moiety in urine are maintained for at least 24 hrs after a 3-g single-dose administration.
About 18-28% of the dose is excreted in feces with enterohepatic recirculation.
INDICATIONS: Acute bacterial cystitis, acute episode in relapsing bacterial cystitis, acute bacterial urethrovesical syndrome, nonspecific bacterial urethritis.
Significant asymptomatic bacteriuria (in pregnancy).
Prophylaxis of urinary tract infection in surgery and transurethral diagnostic maneuvers.
DOSAGE & ADMINISTRATION: One sachet (3 g fosfomycin trometamol) as a single-dose regimen.
Clinical symptoms usually disappear 2-3 days after beginning of treatment.
Acute infections of the lower urinary tract (cystitis, nongonococcal urethritis) caused by susceptible microorganisms: Single dose.
The persistence of local symptoms, if any, after treatment, is not necessarily a sign of therapeutic failure but usually the consequence of the past inflammation.
In more clinically problematic case (elderly, bedridden patients, recurrent infections) or in infections due to microorganisms usually susceptible to the highest antibiotic dose (Pseudomonas, Enterobacter, indole-positive Proteus), two doses can be administered at a 24-hr interval.
Prophylaxis of urinary infections following surgery and transurethral diagnostic maneuvers: Usually 2 doses. The 1st dose is administered 3 hrs before the intervention and the 2nd dose 24 hrs after the 1st dose.
Administration: Monurol must only be administered orally on an empty stomach, preferably at bedtime, after emptying the bladder. The dose must be dissolved in a glass of water or in another nonalcoholic drink and administered soon after dissolving.
CONTRAINDICATIONS: Hypersensitivity to fosfomycin trometamol.
PRECAUTIONS: Meals can retard the absorption of fosfomycin trometamol, with consequent slight decrease in blood and urinary levels. Therefore, Monurol should be taken on an empty stomach, 2-3 hrs apart from meals.
Use in pregnancy & lactation: During pregnancy, in lactating patients and infants, the drug should only be administered in case of real necessity and under direct medical supervision.
ADVERSE REACTIONS: Monurol is particularly well-tolerated by adults and children. Gastrointestinal disorders (nausea, heartburn, diarrhea) and skin rashes have been rarely observed and they regressed spontaneously and rapidly without any particular counter-treatment.

RINOFLUIMUCIL

CONTENTS: Acetylcysteine, tuaminoheptane sulfate.
PRESENTATION: Spray 10 mL (with nebulizer).
DESCRIPTION: Each 100 mL of solution contains acetylcysteine 1 g and tuaminoheptane sulfate 0.5 g.
ACTIONS: Pharmacology: Rinofluimucil is specifically studied to obtain mucolytic and decongestant effects. The main constituent of this combination is represented by N-acetylcysteine whose rapid fluidifying action on the mucous and mucopurulent secretions, is due to the breaking of the disulfide bond of glycoproteic constituent of mucous.
Tuaminoheptane sulfate is a sympathomimetic amine which, by topical application, exerts a vasoconstrictive action, without systemic effects.
Pharmacokinetics: It was observed that the single ingredients of the medicinal specialty are not observed in active doses by systemic route.
Toxicology: Rinofluimucil was shown to have a good tolerability both in terms of local and systemic effects.
INDICATIONS: Acute and subacute rhinitis, with mucopurulent and torpid exudate; chronic and mucocrustous rhinitis; vasomotor rhinitis; sinusitis.
DOSAGE & ADMINISTRATION: Rinofluimucil is used for applications into the nasal cavities by means of an appropriate dosing dispenser.
Adults: 2 puffs/nostril 3-4 times/day. ***Children:*** 1 puff/nostril 3-4 times/day.
Do not exceed the recommended doses.
The use of topical products, especially if prolonged, may cause sensitization phenomena. If these occur, the treatment must be suspended and, whenever necessary, an appropriate therapy is to be done. However, in the absence of a therapeutic response within few days, consult a physician. In any case, the treatment must not be prolonged >7 days.
CONTRAINDICATIONS: Known hypersensitivity to acetylcysteine or tuaminoheptane sulfate. Narrow-angle glaucoma. Hyperthyroidism. Rinofluimucil should not be used together within 2 weeks after treatment with antidepressants.
PRECAUTIONS: Do not swallow. Avoid contact with the eyes. In patients suffering from cardiovascular diseases,