

# Fosfomycin tromethamine (MONUROL)

## Criteria for Use

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VA Pharmacy Benefits Management Services,  
Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.** The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.

**Exclusion Criteria** If the answer to ANY item below is met, then the patient should NOT receive fosfomycin.

- Treatment of systemic infections beyond the urinary tract or prostate
- History of hypersensitivity reaction to fosfomycin
- Pyelonephritis or perinephric abscess
- Asymptomatic bacteriuria unless the patient is scheduled to undergo significant urinary manipulation or is pregnant

**Inclusion Criteria - At least one of the following inclusion criteria must be fulfilled.**

- Cystitis with *Escherichia coli* or *Enterococcus spp.* in urine culture which is non-susceptible to other appropriate oral agents (e.g. nitrofurantoin, beta-lactams, trimethoprim-sulfamethoxazole) OR have a severe allergy or contraindication to other susceptible oral agents
- Acute/chronic prostatitis with *Escherichia coli* or *Enterococcus spp.* in culture which is non-susceptible to other appropriate oral agents (e.g. trimethoprim-sulfamethoxazole, doxycycline, fluoroquinolones) OR have a severe allergy or contraindication to other susceptible oral agents
- Other locally-approved indication or patient situation \_\_\_\_\_

### Dosage and Administration

Acute uncomplicated cystitis in females (FDA-approved): 3 grams orally once with or without food.

Complicated cystitis in females or males: 3 grams orally once every 2-3 days for 3 doses has been utilized for multi-drug resistant UTI; although unclear if this dosing is more efficacious than a single dose.

Acute/chronic prostatitis (off-label): 3 g orally daily for one week, followed by 3 g orally every 48 hours, OR 3 g orally every 48 to 72 hours; durations: acute – 2 to 4 weeks, chronic – 4 to 6 weeks

### Supplemental Information

- Fosfomycin is FDA-approved for *Escherichia coli* and *Enterococcus faecalis* uncomplicated urinary tract infection (UTI), which by definition excludes males. However, studies demonstrate it is likely a safe and efficacious option for complicated UTI in males only involving the bladder
- Overall, ESBL *E.coli* fosfomycin resistance rates are low. A systematic review of 84 studies showed susceptibility rates from 81-100%
  - Fosfomycin should be reserved for *E. coli*, as several other gram-negative organisms (*Klebsiella spp*, *Enterobacter spp*, *Serratia marcescens*, *Pseudomonas aeruginosa*) intrinsically have the fosA gene, leading to hydrolysis and clinical failure of fosfomycin.
- Fosfomycin does not achieve adequate concentration in the renal parenchyma and should be avoided for pyelonephritis and complicated UTI.
- Fosfomycin may be considered (off-label) for the treatment of bacterial prostatitis. However, since the evidence for treatment of chronic prostatitis is more robust for fluoroquinolones than for fosfomycin, fluoroquinolones, if susceptible, may be generally preferred over fosfomycin for treatment of prostatitis