

## FIRST TIME GENERIC APPROVAL

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|--------------------------|-------------------------|
| <b>Brand Name</b>        | Monurol®                |
| <b>Generic Name</b>      | fosfomycin tromethamine |
| <b>Drug Manufacturer</b> | Xiromed                 |

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First Time Generic Approval

#### FDA APPROVAL DATE

October 6, 2020

#### LAUNCH DATE

October 6, 2020

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 212548

#### DISPENSING RESTRICTIONS

Open Distribution

### Overview

#### INDICATION FOR USE

Fosfomycin tromethamine is indicated only for the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of *Escherichia coli* and *Enterococcus faecalis*. Monurol® is not indicated for the treatment of pyelonephritis or perinephric abscess.

#### MECHANISMS OF ACTION

Fosfomycin is a bactericidal antibiotic that interferes with cell wall synthesis in both Gram-positive and Gram-negative bacteria by inhibiting the initial step involving phosphoenolpyruvate synthetase. Fosfomycin enters the cells of fosfomycin-susceptible bacteria by means of two different transport uptake systems: a constitutively functional l- $\alpha$ -glycerophosphate transport system (GlpT) and the hexose-phosphate uptake system (UhpT). It inhibits the synthesis of peptidoglycan by blocking the formation of N-acetylmuramic acid.

#### DOSE FORM AND STRENGTH

Single-dose oral packet: 3 g

#### DOSE & ADMINISTRATION

The recommended dosage for women  $\geq 18$  years of age: 1 packet orally. May be taken with or without food. Should not be taken in its dry form. Always mix with water before ingesting.

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