RXADVANCE
2 Park Central Drive
Southborough, MA 01772

FIRST TIME GENERIC APPROVAL

Brand Name	Monurol®
Generic Name	fosfomycin tromethamine
Drug Manufacturer	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-α-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 ≥ 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.