

National Essential Medicines List International Price Comparison
Adult Hospital Level
Component: Kidney and urology

Date: 23February 2016
Medication: Fosfomycin
Indication: Urinary tract infection

Reviewer: National Department of Health Pricing Committee

Medicine Overview

Fosfomycin tromethamine is rapidly absorbed following oral administration and converted to the free acid, fosfomycin. Absolute oral bioavailability under fasting conditions is 37%. After a single 3-gm dose of MONUROL, the mean (\pm 1 SD) maximum serum concentration (C_{max}) achieved was 26.1 (\pm 9.1) μ g/mL within 2 hours. The oral bioavailability of fosfomycin is reduced to 30% under fed conditions. Following a single 3-gm oral dose of MONUROL with a high-fat meal, the mean C_{max} achieved was 17.6 (\pm 4.4) μ g/mL within 4 hours. Fosfomycin is excreted unchanged in both urine and faeces.

Fosfomycin (the active component of fosfomycin tromethamine) has *in vitro* activity against a broad range of gram-positive and gram-negative aerobic microorganisms which are associated with uncomplicated urinary tract infections. Fosfomycin is bactericidal in urine at therapeutic doses. The bactericidal action of fosfomycin is due to its inactivation of the enzyme enolpyruvyl transferase, thereby irreversibly blocking the condensation of uridine diphosphate-N-acetylglucosamine with p-enolpyruvate, one of the first steps in bacterial cell wall synthesis. It also reduces adherence of bacteria to uroepithelial cells. There is generally no cross-resistance between fosfomycin and other classes of antibacterial agents such as beta-lactams and aminoglycosides. [Rxlist.com, downloaded 20 February 2016]

MONUROL (trade name for fosfomycin) 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.

If persistence or reappearance of bacteriuria occurs after treatment with MONUROL, other therapeutic agents should be selected. The recommended dosage for women 18 years of age and older for uncomplicated urinary tract infection (acute cystitis) is one sachet of MONUROL. [Rxlist.com, downloaded 22 February 2016]

Medicine Price Overview

Prices were sourced for different countries. The 4 countries in the South African Draft International Benchmarking Methodology were also sought. The medicine does not feature on the public lists of Australia and New Zealand and up to 2014 was not registered in either country. No price was made available by Spain. Canada is included in the table below. The prices included were in comparison to the existing medicine on the South African market. Other dosage forms were not included.

Country	Trade Name	Active Ingredient	Pack description for Public Sector price provided	Manufacturer Price in Rands in the Public Sector	Pack description for Private Sector price provided	Manufacturer Price in Rands in the Private Sector
South Africa	Urizone	fosfomycin			3g per sachet	149.63
Austria	Monuril 3 g Granulate	fosfomycin	3g granulate	57.09		
Hungary	Monural	fosfomycin	3g per sachet	36.58		36.58
	Fosfomycin Exeltis		3g per sachet	21.93		21.93
Turkey	Monurol	fosfomycin	3g per sachet	49.04		
Czech Republic	RAPIDNORM 3000 MG	fosfomycin			POR GRA SOL 1X3GM	82.82
Russia	Monural	fosfomycin			2g per sachet	94.32
	Monural	fosfomycin			3g per sachet	83.27
Bulgaria	MONURAL	Fosfomycin (fosfomycin trometamo)	3 g granules for oral solution x 1			78.85
Canada	Monurol Sachet	fosfomycin	3g per dose	176.48		
Germany	Monuril	fosfomycin	3000 mg	86.48		
	Fosfuro	fosfomycin	3000 mg	73.76		
	InfectoFos	fosfomycin	3000 mg	274.29		