

Prescribing Protocol - FOSFOMYCIN	
Title	Fosfomycin Oral Prescribing Protocol
Areas where Protocol/Guideline applicable e.g., District, Hospital, ITU, Ward	Inpatient ward areas including intensive care
Areas where Protocol/Guideline not applicable	Outpatient
Authorised Prescribers	Infectious Diseases physician or Microbiologist
Indication for use	<p>Acute uncomplicated cystitis in females > 18 years due to susceptible pathogens including <i>E. coli</i>, <i>E. faecalis</i> when other agents are unsuitable or ineffective (oral).</p> <p>Bacterial infections due to susceptible organism, e.g., complicated cystitis when other agents are unsuitable or ineffective</p> <p>Fosfomycin has activity against Gram- negative bacteria, including organisms producing extended- spectrum beta-lactamase enzymes (ESBLs) (except <i>Pseudomonas aeruginosa</i>) and Enterococcus species (including vancomycin- resistant enterococci [VRE]).</p>
Clinical condition	Oral agent available for cystitis caused by ESBL producing Gram-negative bacteria or Enterococcus species (including VRE) when alternative oral agents are unsuitable or ineffective.
Contra-indications	Known hypersensitivity to fosfomycin trometamol, or its excipients.
Precautions	<p>Nervous system: headache, dizziness, paraesthesia</p> <p>Cardiac system: tachycardia, hypotension</p> <p>Gastrointestinal system: diarrhoea, nausea, dyspepsia, abdominal pain, anorexia, dry mouth, flatulence.</p> <p>Patients with severe renal insufficiency (creatinine clearance <10mL/min)</p>
Place in Therapy	<p>Oral option for acute cystitis caused by ESBL producing bacteria or Enterococcus species (including VRE) if alternative oral agents (i.e., nitrofurantoin) are unsuitable or ineffective.</p> <p>Guidance red drug: prior ID/Micro approval required.</p> <p>Only to be stocked in Pharmacy.</p>
If part of combination therapy, list other drugs	N/A
Dosage (Include dosage adjustment for specific patient groups)	<p>Uncomplicated Cystitis: 3 grams orally stat (once).</p> <p>Complicated Cystitis: 3 grams orally every three days for 3 doses.</p>
Duration of therapy	Treatment duration for cystitis is either 1 - 3 doses and not for pyelonephritis/ complicated infection requiring prolonged duration.

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Important Drug Interactions	Metoclopramide may lower fosfomycin serum concentration and urinary excretion
Administration instructions	<p>Fosfomycin 3 gram (contents of 1 sachet) should be dissolved in a glass of water as a single dose and taken immediately after its preparation.</p> <p>Should be taken on empty stomach (i.e., at least one hour before food or two hours after food)</p>
Monitoring requirements	Resolution of clinical signs and symptoms, improvement in laboratory parameters/testing.
Management of complications	Consideration of discontinuation of therapy and management of the specific complication, if severe.
Basis of Protocol/Guideline	<ol style="list-style-type: none"> 1. Matthews P C et al, Oral fosfomycin for treatment of urinary tract infection; a retrospective cohort study, BMC Infec Dis 2016 2. MIMS Online [Internet]. Crows Nest (NSW): MIMS Australia Pty Ltd; 2019. Fosfomycin; [updated 2017 Sept 9; cited 2019 October 10]. 3. Pullukcu H et al. Fosfomycin in treatment of extended spectrum beta-lactamase-producing <i>Escherichia coli</i>-related lower urinary tract infections. IJAA (2007) 29: 62-65. 4. Senol S et al. Carbapenem versus fosfomycin tromethanol in treatment of extended-spectrum beta-lactamase-producing <i>Escherichia coli</i>-related complicated lower urinary tract infection. J Chemotherapy (2010) 22(5): 355-7. 5. TGA Product Information available online for fosfomycin (Monurol) 6. The Sanford Guide to Antimicrobial Therapy 2019. 50th ed. 7. Huttner A, Kowalczyk A, Turjeman A, et al. Effect of 5-day Nitrofurantoin vs Single-Dose Fosfomycin on Clinical Resolution of Uncomplicated Lower Urinary Tract Infection in Women. JAMA. 2018; 319(17):1781-1789. 8. Neuner EA, Sekeres J, Hall GS, van Duin D. Experience with Fosfomycin for Treatment of Urinary Tract Infections Due to Multidrug-Resistant Organism. Antimicrobial Agents and Chemotherapy. 2012; 56(11): 5744-5748.
Groups consulted in development of this protocol	DIDISH, AMS CAAG (SESLHD/ISLHD)

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GOVERNANCE	
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