

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>
<p>Clinical condition</p> <p>Patient selection: Inclusion criteria (list investigations necessary and relevant results)</p>	<p>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.</p>
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)	Uncomplicated Cystitis: 3 grams orally stat (once). Complicated Cystitis: 3 grams orally every three days for 3 doses.
Duration of therapy	Treatment duration for cystitis is either 1-3 doses and not for pyelonephritis/ complicated infection requiring prolonged duration.
Important Drug Interactions	Metoclopramide may lower fosfomycin serum concentration and urinary excretion
Administration instructions	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. Should be taken on empty stomach (i.e. at least one hour before food or two hours after food)
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 (including sources of evidence, references)	<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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**Fosfomycin Oral
Prescribing Protocol - SESLHDPR/661**

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GOVERNANCE	
Enactment date	18 th December 2020
Expiry date: (maximum 36 months from date of original approval)	31 st December 2022
Ratification date by SESLHD QUM Committee	5 th December 2019
Chairperson, QUM Committee	Prof George Rubin
Version Number	1.0