Fosfomycin (oral) Monograph - Paediatric

**Scope (Staff):** Clinical Staff – Medical, Nursing, Pharmacy

**Scope (Area):** Perth Children’s Hospital (PCH)

**Child Safe Organisation Statement of Commitment**
The Child and Adolescent Health Service (CAHS) commits to being a child safe organisation by meeting the National Child Safe Principles and National Child Safe Standards. This is a commitment to a strong culture supported by robust policies and procedures to ensure the safety and wellbeing of children at CAHS.

**DESCRIPTION**
- Fosfomycin inhibits peptidoglycan synthesis and interferes with bacterial cell wall synthesis resulting in bacterial cell lysis.\(^{(1, 2)}\)

**INDICATIONS AND RESTRICTIONS**
- Fosfomycin is active against a range of Gram-positive and Gram-negative bacteria including multi-resistant Gram negative bacteria (e.g. Extended Spectrum beta-lactamase’s). It is not active against *Pseudomonas aeruginosa*.\(^{(3, 4)}\)
- Fosfomycin should be reserved for treatment of urinary tract infections resistant to other antibiotic agents. It is generally not suitable for pyelonephritis as adequate systemic concentrations are not achieved.\(^{(1, 3)}\)

*Oral : Restricted (red) antibiotic*
- ChAMP approval is required prior to prescription. Document the indication, the ChAMP approver, and the date and time on the prescription or in the medication chart indication box.

**CONTRAINDICATIONS**
- Fosfomycin is contraindicated in patients with a hypersensitivity to fosfomycin or any of the excipients.\(^{(5, 6)}\)
- Contraindicated in patients with severe renal insufficiency (creatinine clearance <10mL/min), patients undergoing haemofiltration, haemodialysis or peritoneal dialysis.\(^{(6)}\)

**PRECAUTIONS**
- Doses should be prescribed as fosfomycin base as there are different salt formulations available which are not equivalent.\(^{(4, 7)}\)
- Fosfomycin sachets should be used with caution in patients with fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency as each sachet contains 2.2 grams of sucrose.\(^{(1)}\)
## FORMULATIONS

<table>
<thead>
<tr>
<th>Available at PCH</th>
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<tbody>
<tr>
<td>• 3gram sachet as fosfomycin trometamol</td>
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<tr>
<td>• IV Powder for reconstitution-vial (not covered in this monograph refer to: Intravenous Fosfomycin Monograph - Paediatric) (available via Special Access scheme - SAS)</td>
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**Other formulations:**

| • 500mg capsule as fosfomycin calcium (available via Special Access scheme - SAS) |

## DOSAGE

- The doses listed below fall within the standard range.
- Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant.

**Doses should be prescribed as fosfomycin base as there are different salt formulations available which are NOT equivalent.**

**Neonates (less than 30 days of age):**

| • Fosfomycin trometamol is not routinely used in neonates. |

**Children ≥ 1 month: treatment of UTI's only**

- **Children <1 year old:** 1 gram (of fosfomycin base) as a single dose.\(^{(8, 9)}\)
- **Children 1 to 12 years old:** 2 grams (of fosfomycin base) as a single dose.\(^{(8, 10)}\)
- **Children ≥12 years old:** 3 grams (of fosfomycin base) as a single dose.\(^{(8, 10)}\)
- **Dose may be repeated after 2 to 3 days in patients on advice from Infectious Diseases.**\(^{(5, 11)}\)

## DOSAGE ADJUSTMENT

**Dosage adjustment required in renal impairment:**

- To calculate the estimated glomerular filtration rate in children ≥1 year (eGFR) use the formula available via the following eGFR calculator.\(^{(12)}\) This formula should only be used for children older than one year
- Limited information is available regarding dosage adjustment of oral fosfomycin in renal failure.
- Dosage adjustment is required in patients with a creatinine clearance less than 40mL/minute.
- Fosfomycin trometamol is contraindicated in severe renal insufficiency (creatinine clearance <10mL/min).\(^{(4)}\)
- The half-life of fosfomycin increases and urinary excretion decreases as renal function decreases. Contact Pharmacy for
| RECONSTITUTION | 3gram sachet as fosfomycin trometamol.  
- Dissolve the contents of a single sachet in 90 to 125mL of cool water for reconstitution and stir to dissolve. Do not dissolve in hot water.\(^{(2, 13)}\)  
- Administer immediately.  
- If a part dose is required dissolve the contents of the 3gram sachet in 90mL of cool water for reconstitution. Each 30mL of the resulting solution contains 1gram. Discard any remaining solution. |
| ADMINISTRATION | \- Fosfomycin may be taken without regard to food.\(^{(1, 2, 5, 13)}\)  
- For fosfomycin trometamol, once dissolved in cool water, the solution should be taken immediately.\(^{(2, 13)}\) |
| MONITORING | \- Patients should be monitored for clinical cure of the urinary tract infection.\(^{(5)}\) |
| ADVERSE EFFECTS | \- **Common:** asthenia, diarrhoea, dizziness, weakness, dyspepsia, headache, nausea and vomiting, rash, vulvovaginal infection, abdominal pain, back pain, dysmenorrhoea, pharyngitis and rhinitis.\(^{(2, 7)}\)  
- **Rare:** antibiotic associated colitis, paraesthesia, hypersensitivity reaction s (e.g. anaphylaxis, angioedema, rash)\(^{(1, 4)}\) |
| COMPATIBLE FLUIDS | \- Not applicable |
| STORAGE | \- Store below 25°C\(^{(6)}\) |
| INTERACTIONS | \- **Fosfomycin may interact with other medications; please consult PCH approved references (e.g. Clinical Pharmacology), your ward pharmacist or Pharmacy on extension 63546 for more information.**  
- Metoclopramide (and other prokinetic agents) may reduce the absorption of fosfomycin; separating the time of administration may limit the interaction.\(^{(2)}\)  
- Antimicrobial synergy has been seen with some beta-lactam antibiotics.\(^{(7)}\)  
- Use of fosfomycin with urinary alkalinisers (e.g. Ural\(^{®}\) or Citravescent\(^{®}\)) within 48 hours after dosing is not recommended. Fosfomycin is most bactericidal at typical urinary pH. Also, potential for resistance development appears |
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<td>• 1.9g of fosfomycin trometamol is equivalent to 1gram of fosfomycin base.(^1)</td>
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<td>• Each 3gram sachet of fosfomycin trometamol contains 2.2g of sucrose.(^1)</td>
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| MANUFACTURER SAFETY DATA SHEET (SDS)                                    | To access to the Manufacturer SDS for this product, use the following link to ChemAlert. |

**Please note: The information contained in this guideline is to assist with the preparation and administration of fosfomycin. Any variations to the doses recommended should be clarified with the prescriber prior to administration**

**Related CAHS internal policies, procedures and guidelines**

- Antimicrobial Stewardship Policy
- ChAMP Empiric Guidelines and Monographs
- KEMH Neonatal Medication Protocols

**References and related external legislation, policies, and guidelines**

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This document can be made available in alternative formats on request for a person with a disability.

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NSMHS: N/A
Child Safe Standards: N/A

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