Hospital Guidance

Fosfomycin – Information for Prescribers

NHS Lanarkshire

This information is provided to facilitate the prescribing and supply of fosfomycin in the secondary care setting. For full prescribing information please consult the product SPCs.

Therapeutic indications	1. Urinary Tract Infection (UTI) (± catheter) caused by Gram negative organisms with proven susceptibility to Fosfomycin and resistant to all other suitable antibiotics, and where no alternative agent is available. **Only treat if symptomatic. Do not treat asymptomatic bacteriuria. Send urine culture.** 2. Other conditions as advised by Infection Specialist
Dosing Advice, Length of Treatment & Administration	ORAL: **Uncomplicated UTIs in non-pregnant adult females, or adolescent females aged 12-17 years:** One 3g sachet as a one off dose **Lower UTI in adult men:** One 3g sachet, repeat a further 3g sachet 72 hours later (total of 2 doses per treatment)* **Catheter-associated UTI (CAUTI) in non-pregnant adult females and adult men:** If catheterised, catheter must be changed or removed. One 3g sachet, repeat a further 3g sachet 72 hours later (total of 2 doses per treatment)* **Administration:** Dose to be given preferably at night and after bladder emptying. The sachet should be dissolved in water and taken immediately after preparation on an empty stomach (about 2-3 hours before or 2-3 hours after a meal). **Note:** **Lower UTI treatment with the oral preparation in men and CAUTI is not licensed and therefore use in these patients is 'off-label', but is recognised in standard clinical practice. A blanket unlicensed form has been completed for use in NHS Lanarkshire.*
	IV: **Only on Infection Specialist advice or if reported as susceptible on microbiology report relevant to episode of infection (ALERT antibiotic)⁺** **Complicated UTI (IV therapy):** 12-16g daily in 2-3 divided doses. If catheterised, catheter must be changed or removed. **Note:** *The daily dose of IV fosfomycin is based on the indication, severity and site of infection, susceptibility of pathogen(s) to fosfomycin and the patient's estimated creatinine clearance. The high dose regimen should be used in severe infections with organisms known or suspected to be less susceptible. Individual doses must not exceed 8g.* **Administration**: *Full details available from Medusa monograph or SPC.* **Note: Indication for IV therapy should be reviewed daily.** Contact Infection Specialist for advice on use for other indications, and for IV to oral switch recommendations.
Contraindications	• Known hypersensitivity to fosfomycin or product excipients • Contraindicated in Creatinine Clearance (CrCl) < 10ml/min • Oral administration not suitable for upper UTI/pyelonephritis

Updated by: C. MacDonald | Approved by: Antimicrobial Management Committee April 2023, ADTC May 2023| Last update: June 2023| Review: April 2026

Renal impairment	ORAL: no adjustment needed for CrCl > 10ml/min. Contraindicated in CrCl < 10ml/min. IV: See SPC / contact pharmacy for dosing advice in renal impairment. Dose reduction will be required if CrCl < 40ml/minute.
Adverse Effects ***Frequency:*** *Very common ≥ 1/10,* *Common ≥ 1/100 - <1/10* *Uncommon ≥ 1/1000 - <1/100* *Rare ≥ 1/10,000 - <1/1000* *Very rare <1/10,000*	*See BNF and SPCs for full list.* ORAL: most common adverse reactions involve the gastrointestinal tract, mainly diarrhoea. These events are usually self-limited in duration and resolve spontaneously. IV: most commonly reported adverse reactions during treatment are erythematous skin eruption, hypernatraemia, hypokalaemia, injection site reactions, dysgeusia and gastrointestinal disturbances. Other important adverse reactions include anaphylactic shock and hepatic disorders (very rare), antibiotic associated colitis, confusion and decreases in white blood cell counts (frequency not known). Reporting suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system website: www.mhra.gov.uk/yellowcard
Interactions	• Metoclopramide: Concomitant administration of metoclopramide has been shown to lower serum and urinary concentrations of fosfomycin and should be avoided. Other medicinal products that increase gastrointestinal motility may produce similar effects. • Alterations in INR: Monitor for increased oral anticoagulant activity. • Food effect: Food may delay absorption of oral fosfomycin, with consequent slight decrease in peak plasma levels and urinary concentrations. Therefore, should administer oral fosfomycin on an empty stomach (2–3 hours before or after a meal).
Preparations Available	Oral – Fosfomycin 3g sachet (fosfomycin trometamol) Injection – Fomicyt™ (fosfomycin sodium) 40mg/ml. Available as 2g or 4g vials powder for solution for infusion vials. Note: High sodium content; 1g of Fomicyt™ contains 14 mmol (320mg) of sodium.
References	1. Joint Formulary Committee. *British National Formulary* (online) London: BMJ Group and Pharmaceutical Press. Accessed March 2023 via http://www.medicinescomplete.com 2. Zambon UK Limited. Summary of Product Characteristics – Monuril™ 3g granules for oral solution. Accessed from: https://www.medicines.org.uk/emc/product/7329/smpc [last updated June 2021] 3. Infectopharm. Summary of Product Characteristics – Fomicyt™ 40mg/ml powder for solution for infusion. Accessed from: https://products.mhra.gov.uk/ [last updated March 2021]
Further Information	* Unlicensed dose + See Alert (Protected) Antimicrobial Authorisation Pathway Further guidance can be obtained from Infection Specialist and/or antimicrobial pharmacists.