FOSFOMYCIN

PRESCRIBING INFORMATION

TARGET AUDIENCE	Clinical teams prescribing fosfomycin for patients within NHS Lanarkshire.
PATIENT GROUP	Females aged >12 years and adult males

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Fosfomycin: Prescribing Information

1. Therapeutic Indications

- Symptomatic Urinary Tract Infection (UTI) (± catheter) caused by Gram negative organisms with proven susceptibility to fosfomycin and resistant to all other suitable antibiotics, where no alternative agent is available.
- Other conditions as advised by Infection Specialist
- IV fosfomycin is an ALERT (protected) antimicrobial and should only be prescribed on the advice of a microbiologist or ID physician.

2. Dosing Advice

2.1 Oral Fosfomycin

Indication	Oral Fosfomcyin Dose
Uncomplicated UTIs in non-pregnant females aged > 12 years	One 3g sachet as a single 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	One 3g sachet, repeat a further 3g sachet 72 hours later (total of 2 doses per treatment)*

*Lower UTI treatment in men and CAUTI treatment 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'

Take fosfomycin sachets on an empty stomach (about 2-3 hours before or after a meal), preferably before bedtime and after emptying the bladder. Dissolve the dose into a glass of water and take immediately.

2.2 IV Fosfomycin

- Only on Infection Specialist advice or if reported as susceptible on microbiology report relevant to episode of infection (ALERT (protected) antimicrobial).
- Complicated UTI: 12-24g daily in 2-3 divided doses. Review indication for IV therapy daily. If catheterised, catheter must be changed or removed.
- Daily dose 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.
- Limited safety data in particular for doses in excess of 16 g/day. Special caution is advised when such doses are prescribed.

3. Dose Adjustments in Renal / Hepatic Impairment

ORAL: No adjustment needed for Creatinine Clearance (CrCl) > 10ml/min. Contraindicated in CrCl < 10ml/min. No dose adjustment is necessary in patients with hepatic impairment.

IV: See SPC / contact pharmacy for dosing advice in renal impairment. Dose reduction will be required if CrCl < 40ml/minute. No dose adjustment is necessary in patients with hepatic impairment.

4. Contraindications and Cautions

4.1 Contraindications:

- Hypersensitivity to the active substance or to any of the excipients

With oral:

- CrCl < 10 ml/min
- Patients undergoing haemodialysis and peritoneal dialysis
- Not suitable for upper UTI/pyelonephritis

4.2 Cautions:

- With IV: Cardiac insufficiency, Elderly (high doses), Hyperaldosteronism, Hypernatraemia, Hypertension, Pulmonary oedema

5. Adverse Effects

This list is not exhaustive. For full list of side effects see BNF/SPC.

- ORAL: most common adverse reactions involve gastrointestinal nausea, diarrhoea, headache and vulvovaginal infections. These events are usually self-limited in duration and resolve spontaneously.
- IV: most commonly reported adverse reactions 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)

Report any suspected serious adverse reactions via the Yellow Card Scheme.

6. Interactions with Fosfomycin

- 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).

7. References/Evidence

1. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. Accessed February 2026 via http://www.medicinescomplete.com
2. Zambon UK Ltd. Summary of Product Characteristics for Monuril 3g granules for oral solution. Last updated 01/06/2021. Accessed via www.medicines.org.uk
3. InfectoPharm Ltd. Summary of Product Characteristics for Fomicyt 40 mg/ml powder for solution for infusion. Last updated 16/01/2025. Accessed via www.medicines.org.uk
4. Renal Drug Database – Fosfomycin monograph. Last updated 11/06/2024. Accessed via https://www.renaldrugdatabase.com/s/article/FOSFOMYCIN

Appendices

Governance information for Guidance document

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CONSULTATION AND DISTRIBUTION RECORD	
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CHANGE RECORD

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February 2026	Amy Thomson (on behalf of the AMC)	• Formatting changes • Dose for IV changed from 12-16g to 12-24g as per SPC with additional information added about the limited safety data above 16g • Dialysis contra-indications added • Cautions added	2026.1