

Product Update:

fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt®)
SMC No. (1033/15)

Nordic Pharma

06 February 2015

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

fosfomycin (Fomicyt®) is accepted for restricted use within NHS Scotland.

Indication under review: for the treatment of the following infections in adults and children including neonates:

- Acute osteomyelitis
- Complicated urinary tract infections
- Nosocomial lower respiratory tract infections
- Bacterial meningitis
- Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above

Fosfomycin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections listed above, or when these alternative antibacterial agents have failed to demonstrate efficacy.

Consideration should be given to national guidance on the appropriate use of antibacterial agents.

SMC restriction: initiation by microbiologists or infectious disease specialists.

Unlicensed preparations of intravenous fosfomycin are commonly used in the NHS in Scotland to treat multi-drug resistant gram negative organisms. This provides a licensed preparation. Estimated patient numbers are expected to be small.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 04 December 2014.

**Vice Chairman
Scottish Medicines Consortium**