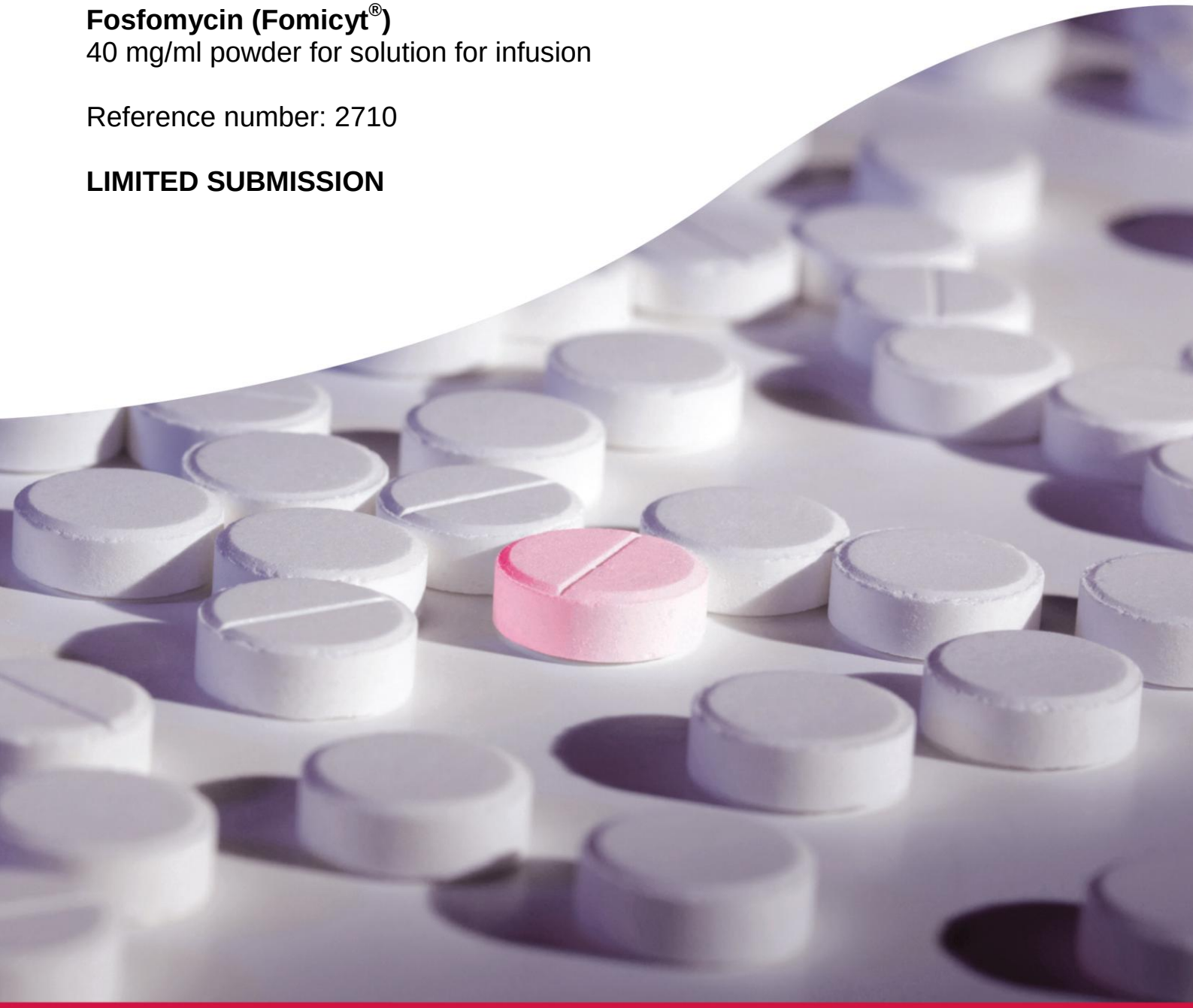
All Wales Therapeutics and Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

**AWMSG SECRETARIAT ASSESSMENT REPORT**

**Fosfomycin (Fomicyt®)**
40 mg/ml powder for solution for infusion

Reference number: 2710

**LIMITED SUBMISSION**



This report has been prepared by the All Wales Therapeutics and Toxicology Centre (AWTTC), in collaboration with the Centre for Health Economics & Medicines Evaluation, Bangor University.

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## AWMSG Secretariat Assessment Report – Limited submission

### Fosfomycin (Fomicyt®) 40 mg/ml powder for solution for infusion

**Company: Nordic Pharma UK Ltd**

**Date of submission: 10/06/2015**

**Licensed indication under consideration:**

Fosfomycin (Fomicyt®) 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 (Fomicyt®) 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.

The applicant company suggest that use should be restricted to microbiologist or specialist in infectious diseases prescribing and that use of fosfomycin should be considered as an option for the treatment of infections associated with methicillin-resistant *Staphylococcus* spp., multidrug resistant Enterobacteriaceae and multidrug resistant *Pseudomonas aeruginosa* in the licensed indications.

**Marketing authorisation date: 19 June 2013**

## Comparator(s):

The applicant company suggest that there are no suitable comparators as fosfomycin should be restricted for use when other intravenous antibiotics are considered ineffective, are contra-indicated, or are not tolerated.

## Limited submission details:

The limited submission criteria were met as the anticipated usage of fosfomycin (Fomicyt®) in NHS Wales is considered to be of minimal budgetary impact.

## Clinical effectiveness:

- Fosfomycin sodium powder for solution for infusion previously received marketing authorisation in Germany in 1980, and its use is well established as an option for multidrug resistant infections across a number of European countries. As such, no bioequivalence, clinical efficacy or safety studies were required by the Medicines and Healthcare Products Regulatory Agency (MHRA). Fosfomycin has a well-established side-effect profile and is generally well tolerated.

- There is an acknowledged rise in levels of antibacterial resistance across Europe requiring the need for new effective treatments.

- In support of their licence application, the company provided the MHRA with substantial information from the literature including more than 60 studies (carried out in more than 1,600 patients). The evidence is, however, derived from a number of smaller trials, case series, or larger trials of wider patient population, which included patients with these infections. Furthermore, most fosfomycin trials are in combination therapy leading to a lack of consistency in the active treatment or control arm in observational studies.

- Fosfomycin is reported to possess a low potential for cross resistance with other classes of antimicrobials. *In vitro* data points towards an increased risk of resistance development and therefore intravenous (IV) fosfomycin is generally used in combination with other antibacterial agents.

- The recommended dose of fosfomycin lies in the range of 12–24 g in divided doses. Each gram of fosfomycin contains 14 mmol (320 mg) of sodium. Due to the high sodium load, a low sodium diet is recommended in addition to serum electrolyte levels and water balance monitoring during therapy.

## Budget impact:

- The applicant company estimates that very few patients would be prescribed fosfomycin if recommended for use within NHS Wales. The company conducted interviews with Welsh clinical experts in infectious diseases to establish the likely use of fosfomycin across a number of health boards. The company extrapolated these figures to the Welsh population and estimated that a maximum of 42 patients annually may be considered eligible for therapy with fosfomycin.

- The company were unable to corroborate estimates of patient numbers using published Welsh information on prevalence/incidence, current antibiotic use and resistance patterns. Clinical experts contacted by the All Wales Therapeutics and Toxicology Centre (AWTTC) have confirmed that an estimate in the region of up to ten patients a year may be a realistic figure.

- IV fosfomycin has previously been imported for unlicensed use in Wales; hospital prescribing data would suggest that there has been minimal prescribing.

- The budget impact is estimated to be £13,500 (ten patients) to £56,700 (42 patients) per year, based on an assumed ten day course of treatment. The company has not included evidence for their assumption on course duration.

- The company has not provided an estimate of the net budget impact within NHS Wales for the next five years due to difficulties in predicting the levels of future resistance.

- Collectively, estimates of budget impact are subject to some uncertainty.

## Additional information:

AWTTC is of the opinion that, if recommended, fosfomycin (Fomicyt®) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

The company do not anticipate that fosfomycin (Fomicyt®) will be supplied by a home healthcare provider.

## Evidence search:

**Date of evidence search:** 25 and 29 June 2015
**Date of range of evidence search:** No date limits were applied to database searches.

## AWMSG review

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTC at AWTTC@Wales.nhs.uk for further information.