COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Fomicyt 40 mg/ml powder for solution for infusion
(fosfomycin sodium)

NL/H/4627/001/DC

Date: 2 March 2023

This module reflects the scientific discussion for the approval of Fomicyt 40 mg/ml powder for solution for infusion. The procedure was finalised in the United Kingdom (UK/H/5784/001/DC). After a transfer in 2018, the current RMS is the Netherlands. The report presented below reflects the original procedure at the time of finalisation in the UK and has not been changed or updated since.

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Mutual Recognition Procedure

Fomicyt 40 mg/ml powder for solution for infusion

(Fosfomycin sodium)

Procedure No: UK/H/5784/001/E001

UK Licence No: PL 15011/0017

INFECTOPHARM Arzneimittel und Consilium GmbH

LAY SUMMARY

Fomicyt 40 mg/ml powder for solution for infusion

(Fosfomycin)

This is a summary of the Public Assessment Report (PAR) for Fomicyt 40 mg/ml powder for solution for infusion. It explains how the application for Fomicyt 40 mg/ml powder for solution for infusion was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use Fomicyt 40 mg/ml powder for solution for infusion.

For practical information about using Fomicyt 40 mg/ml powder for solution for infusion, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fomicyt 40 mg/ml powder for solution for infusion and what is it used for?
Fomicyt 40 mg/ml powder for solution for infusion is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Infectofos 2 g/8 g.

Fomicyt 40 mg/ml powder for solution for infusion is used in adults and children to treat the following infections caused by bacteria:
- Infections of the lung
- Infections of the bones
- Infections of the kidney and bladder
- Infections of the brain (meningitis)

This medicine is used when other antibiotics cannot be used or have not worked.

This medicine can be given alone or in combination with other antibiotics.

How does Fomicyt 40 mg/ml powder for solution for infusion work?
The active ingredient in Fomicyt 40 mg/ml powder for solution for infusion is the antibiotic fosfomycin. Fosfomycin kills certain types of germs (bacteria) by stopping synthesis of the protective bacterial cell wall.

How is Fomicyt 40 mg/ml powder for solution for infusion used?
This medicine is given as an infusion into a vein (a drip) by a doctor or a nurse. The infusion will normally take 15 to 60 minutes, depending on the dose. Usually this medicine is given two, three or four times a day.

The dose given and the frequency of dosing will depend on the type and severity of infection and the patient's kidney function. In children, it also depends on the child's weight and age.

Patients with kidney problems or receiving dialysis may be prescribed a lower dose of this medicine.

In general, premature neonates will receive a daily dose of 100 mg/kg body weight in two divided doses; neonates will receive a daily dose of 200 mg/kg body weight in three divided doses; infants aged 1-12 months (up to 10 kg body weight) will receive a daily dose of 200-300 mg/kg body weight in three divided doses; infants and children aged 1-12 years (10-40 kg body weight) will receive a daily dose of 200-400 mg/kg body weight in three-four divided doses; and adolescents aged 12-18 years and adults (> 40 kg body weight) will receive a daily dose of 12-24 g in two-four divided doses

Individual doses must not exceed 8 g.

Please read section 3 of the package leaflet for detailed information on the duration of treatment.

Fomicyt 40 mg/ml powder for solution for infusion can only be obtained with a prescription.

What benefits of Fomicyt 40 mg/ml powder for solution for infusion have been shown in studies?
No studies were needed because Fomicyt 40 mg/ml powder for solution for infusion is a generic medicine that is given as a solution for infusion and contains the same active substance as its reference medicine, Infectofos 2 g/8 g.

What are the possible side effects of Fomicyt 40 mg/ml powder for solution for infusion?
Because Fomicyt 40 mg/ml powder for solution for infusion is a generic medicine its possible side effects are taken as being the same as those of the reference medicine.

For the full list of all side effects reported with Fomicyt 40 mg/ml powder for solution for infusion, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Fomicyt 40 mg/ml powder for solution for infusion approved?
It was concluded that, in accordance with EU requirements, Fomicyt 40 mg/ml powder for solution for infusion has been shown to be comparable to Infectofos 2 g/8 g. Therefore, the MHRA decided that, as for Infectofos 2 g/8 g, the benefits outweigh the identified risks and recommended that Fomicyt 40 mg/ml powder for solution for infusion can be approved for use.

What measures are being taken to ensure the safe and effective use of Fomicyt 40 mg/ml powder for solution for infusion?
A risk management plan has been developed to ensure that Fomicyt 40 mg/ml powder for solution for infusion is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Fomicyt 40 mg/ml powder for solution for infusion, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Fomicyt 40 mg/ml powder for solution for infusion
Greece, Ireland, Italy, the Netherlands, Poland and the UK agreed to grant a Marketing Authorisation for Fomicyt 40 mg/ml powder for solution for infusion on 4 June 2015.A Marketing Authorisation was granted in the UK for Fomicyt 40 mg/ml powder for solution for infusion on 19 June 2015.

Subsequently, Sweden, Norway, Finland, Denmark and Croatia agreed to grant Fomicyt 40 mg/ml powder for solution for infusion a Marketing Authorisation through a repeat-use procedure. (UK/H/5784/001/E0010) The procedure was completed on 8 November 2016.

The full PAR for Fomicyt 40 mg/ml powder for solution for infusion follows this summary.

For more information about treatment with Fomicyt 40 mg/ml powder for solution for infusion, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in July 2017.

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Scientific discussion

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Competent Authorities of Greece, Ireland, Italy, the Netherlands, Poland and the UK considered that the application for Fomicyt 40 mg/ml powder for solution for infusion (PL 15011/0017; UK/H/5784/001/DC) could be approved. This is a prescription-only medicine (POM).

Fomicyt 40 mg/ml powder for solution for infusion is indicated for the treatment of the following infections in adults and children including neonates:

- 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.

Fomicyt 40 mg/ml powder for solution for infusion 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.

This application was submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and Greece, Ireland, Italy, the Netherlands and Poland as Concerned Member States (CMS). The application for Fomicyt 40 mg/ml powder for solution for infusion was submitted under Article 10(1) of Directive 2001/83/EC, as amended, as a generic application. Fomicyt 40 mg/ml powder for solution for infusion cross-refers to the reference medicinal product Infectofos 2 g/8 g by InfectoPharm Arzneimittel u. Consilium GmbH, registered since May 1980.

Fosfomycin exerts a bactericidal effect on proliferating pathogens by preventing the enzymatic synthesis of the bacterial cell wall. Fosfomycin inhibits the first stage of intracellular bacterial cell wall synthesis by blocking peptidoglycan synthesis.

Fosfomycin is actively transported into the bacterial cell via two different transport systems (the sn-glycerol-3-phosphate and hexose-6 transport systems).

No new non-clinical or clinical data were submitted, which is acceptable given that the application is for an intravenous product which is a generic medicinal product of an originator product that has been in clinical use for over 10 years.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these product types at all sites responsible for the manufacture and assembly of this product. For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

The RMS considers that the pharmacovigilance system, as described by the MA holder, fulfils the requirements and provides adequate evidence that the MA holder has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country. The MA holder has provided a Risk Management Plan (RMP).

The lack of a phase II Environmental Risk Assessment (ERA) with this application for a generic product is acceptable.

The RMS and CMS considered that the application could be approved at Day 210 of the procedure on 4 June 2015. After a subsequent national phase, the Marketing Authorisation was granted in the UK on 19 June 2015.

Fomicyt 40 mg/ml powder for solution for infusion subsequently went through a repeat-use procedure, involving the Sweden, Norway, Finland, Denmark and Croatia. The procedure was completed on 8 November 2016.

II QUALITY ASPECTS

II.1 Introduction

Fomicyt 40 mg/ml powder for solution for infusion is a white to cream-coloured powder.

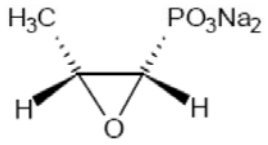
The powder is presented in clear, type-II glass, 100 ml or 250 ml bottles with a rubber stopper (bromobutyl rubber) and pull-off cap. The 100 ml bottles may contain 2 g or 4 g fosfomycin and the 250 ml bottles contain 8 g fosfomycin. Packs of 10 bottles have been authorised. Not all pack sizes may be marketed.

II.2 DRUG SUBSTANCE

INN: Fosfomycin sodium

Chemical name: Disodium (2R, 3S)-(3-methyloxiran-2-yl) phosphonate

Structure:



Molecular formula: $C_3H_5Na_2O_4P$

Molecular weight: 182.02 g/mol

Appearance: A white or almost white, very hygroscopic powder

Solubility: Very soluble in water, sparingly soluble in methanol and practically insoluble in ethanol and methylene chloride

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analyses data that comply with the proposed specification are provided.

Satisfactory Certificates of Analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with foodstuff.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 MEDICINAL PRODUCT

Pharmaceutical Development

The aim of the pharmaceutical development of Fomicyt 40 mg/ml powder for solution for infusion was to develop a generic version of the innovator product, Infectofos 2 g/8 g.

The only excipient in Fomicyt 40 mg/ml powder for solution for infusion is succinic acid, which is controlled in line with the United States Pharmacopoeia monograph. A satisfactory Certificate of Analysis has been provided for this excipient.

The excipient does not contain materials of animal or human origin and no genetically modified organisms (GMO) have been used in the preparation of this excipient.

Manufacturing Process

A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate description of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Control of Finished Product

The finished product specifications are acceptable. Test methods have been described and have been validated adequately. Batch data that comply with the release specifications have been provided. Certificates of Analysis have been provided for all working standards used.

Stability of the Product

Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. Based on the results, a shelf-life of 4 years is acceptable.

II.4 Discussion on chemical, pharmaceutical and biological aspects

It is recommended that a Marketing Authorisation is granted for Fomicyt 40 mg/ml powder for solution for infusion.

II.5 Summaries of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

The SmPC, PIL and labelling are satisfactory and, where appropriate, in line with current guidance.

In accordance with Directive 2010/84/EU, the current version of the SmPC and PIL are available on the MHRA website. See Annex 1.1 for the current labelling.

III NON-CLINICAL ASPECTS

III.1 Introduction

The pharmacodynamic, pharmacokinetic and toxicological properties of fosfomycin are well known. No new non-clinical data have been submitted for this application and none are required.

The applicant has provided an overview based on published literature. The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology

Not applicable, see Section III.1 Introduction, above.

III.3 Pharmacokinetics

Not applicable, see Section III.1 Introduction, above.

III.4 Toxicology

Not applicable, see Section III.1 Introduction, above.

III.5 Ecotoxicity/Environmental Risk Assessment (ERA)

The calculated predicted environmental concentration ($PEC_{Surfacewater}$) for fosfomycin is below the action limit of 0.01 µg/L. It should also be noted that even if a daily dose of 24 g is used when estimating Fpen, the PEC would still be below the action limit.

The Log P is not greater than 4.5. Therefore, screening for persistence, bioaccumulation and toxicity is not necessary. In addition, there are no other environmental concerns apparent regarding the use of Fomicyt 40 mg/ml powder for solution for infusion.

Fomicyt 40 mg/ml powder for solution for infusion is unlikely to represent a risk for the environment following prescribed usage in patients. The performance of a phase II environmental risk assessment is not required.

III.6 Discussion of the non-clinical aspects

It is recommended that a Marketing Authorisation is granted for Fomicyt 40 mg/ml powder for solution for infusion, from a non-clinical point of view.

IV. CLINICAL ASPECTS

IV.1 Introduction.

No new clinical data have been submitted and none are required for an application of this type. The applicant's clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 Pharmacokinetics

In accordance with the guideline on the investigation of bioequivalence the applicant is not required to submit a therapeutic equivalence study if the product is to be administered as an aqueous intravenous solution containing the same active substance, in the same concentration as the reference product (CPMP/EWP/1401/98, subpoint 5.1.6, Parenteral solutions).

IV.3 Pharmacodynamics

The clinical pharmacodynamics properties of fosfomycin are well-known. No new pharmacodynamic data were submitted and none are required for an application of this type.

IV.4 Clinical Efficacy

The clinical efficacy of fosfomycin is well-known. No new efficacy data are presented or are required for this type of application.

IV.5 Clinical Safety

The clinical safety of fosfomycin is well-known. No new safety data were submitted and none are required for this type of application.

IV.6 Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Fomicyt 40 mg/ml powder for solution for infusion.

A summary of risk minimisation measures is listed in the table below:

Summary of risk minimisation measures	
Important identified risks	
Hypernatraemia and/or hypokalaemia	• Routine risk minimisation measures Information and appropriate warnings and precautions on "hypernatraemia and/or hypokalaemia" are mentioned in the SmPC (section 4.4 and 4.8), patient information leaflet (section 2) and labelling. • Additional risk minimisation measures Not necessary
Anaphylactic shock	• Routine risk minimisation measures Information on "anaphylactic shock" is mentioned in the SmPC (section 4.3, 4.4 and 4.8) and patient information leaflet (section 2 and 4).

	• Additional risk minimisation measures Not necessary
Pseudomembranous colitis	• Routine risk minimisation measures Information on "pseudomembranous colitis" is mentioned and explained in the SmPC (section 4.4 and 4.8) and patient information leaflet (section 2 and 4). • Additional risk minimisation measures Not necessary
Use in renal impairment	• Routine risk minimisation measures Information on "use in renal impairment" is mentioned and explained in the section 4.4 of the SmPC, with a cross-reference to section 4.2 and patient leaflet (section 2 and 3). • Additional risk minimisation measures Not necessary
Hepatotoxicity, including fatty liver and hepatitis	• Routine risk minimisation measures Information on "hepatotoxicity, including fatty liver and hepatitis" is mentioned and explained in the SmPC (section 4.8) and patient leaflet (section 4). • Additional risk minimisation measures Not necessary
Haematological reactions, including aplastic anaemia, agranulocytosis and pancytopenia	Routine risk minimisation measures Information on "haematological reactions, including aplastic anaemia, agranulocytosis and pancytopenia" is mentioned in the SmPC (section 4.8) and is mentioned and explained in the patient leaflet (section 4). • Additional risk minimisation measures Not necessary
Important potential risks	
Development of resistance	• Routine risk minimisation measures

	Information on "development of resistance" and advice to prescribers is mentioned in the SmPC (section 4.1, 4.4, and 5.1) and patient information leaflet (section 3). • Additional risk minimisation measures Not necessary
Intra-arterial administration	Routine risk minimisation measures Information on "intra-arterial administration" is mentioned and explained in the section 4.2 of the SmPC and in the patient information leaflet (section "The following information is intended for medical or healthcare professionals only"). Moreover the correct method of administration (infusion into a vein) is given in the PIL sections 1 and 3. • Additional risk minimisation measures Not necessary

Missing information	
Use in pregnant or lactating women	• Routine risk minimisation measures Information on "use of fosfomycin during pregnancy and lactation" including appropriate warnings and recommendations is mentioned in the summary of product characteristics (section 4.6 and 5.3) and patient leaflet (section 2). New information on the risk in pregnant and lactating women will be included in the summary of product characteristics and patient information leaflet as it becomes available. • Additional risk minimisation measures Not necessary
Use in children with renal impairment	• Routine risk minimisation measures Information on the "use of fosfomycin in children with renal impairment" is mentioned in section 4.2 of the SmPC and in the patient information leaflet (section 2 and 3). No dose recommendations can be made in this patient group due to the fact that fosfomycin plasma concentration data for children

	and neonates with renal impairment are currently not available. New information on the pharmacokinetics and posology in children with renal impairment will be included in the summary of product characteristics and patient information leaflet as it becomes available. • Additional risk minimisation measures Not necessary
Limited safety data in particular with high doses in excess of 16 g/day	• Routine risk minimisation measures A statement concerning the "limited safety data of fosfomycin in particular with high doses in excess of 16 g/day" and a warning that individual doses must not exceed 8 g are mentioned in the SmPC (section 4.2). The patients are informed about the upper limit of the individual dose and are advised to inform medical professionals immediately if they think that they have been given an overdose or if they notice certain severe dose related adverse reactions (patient leaflet section 3 and 4). New information on the safety of fosfomycin with high daily doses including overdose effects, previously unknown adverse reactions associated with high doses and pharmacokinetic data will be included in the summary of product characteristics and patient information leaflet as it becomes available. Dosing recommendations will be reassessed in the light of new safety data. • Additional risk minimisation measures Not necessary

The Applicant proposes routine Pharmacovigilance and routine risk minimisation measures for all safety concerns, which is accepted.

IV.7 Discussion of the clinical aspects

It is recommended that a Marketing Authorisation is granted for Fomicyt 40 mg/ml powder for solution for infusion.

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

QUALITY
The important quality characteristics of Fomicyt 40 mg/ml powder for solution for infusion are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type. As the pharmacokinetics, pharmacodynamics and toxicology of fosfomycin are well-known, no additional data were required.

EFFICACY
No new data were submitted and none are required for this type of application.

SAFETY
No new data were submitted and none are required for this type of application.

PRODUCT LITERATURE
The SmPC, PIL and labelling are satisfactory and, where appropriate, in line with current guidance.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with fosfomycin is considered to have demonstrated the therapeutic value of the compound. The benefit/risk assessment is therefore considered to be positive.

RECOMMENDATION
The grant of a Marketing Authorisation is recommended.

Annex 1 - Table of content of the PAR update for MRP and DCP

Steps Taken After the Initial Procedure with an Influence on the Public Assessment Report (Type Ib/II variations, PSURs, commitments)

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
To register a change to the product information. Summary of Product Characteristics (SmPC) sections 4.1, 4.2, 4.3, 4.4, 5.2 and 6.6, the Patient Information Leaflet (PIL) and label have been updated. Some Quality Review of Documents (QRD) template changes have also been made on the PIL.	UK/H/5784/001/II/002	SmPC, PIL, Labelling	01/3/2017	11/06/2017	Approval	Yes

Annex 1.1

Our Reference:	PL 15011/0017, Application 0008
Product	Fomicyt infusion 40 mg/ml
Marketing Authorisation Holder:	Infectopharm Arzneimittel und Consilium GmbH
Active Ingredient(s):	Fosfomycin sodium
Type of Procedure:	Mutual Recognition
Submission Type:	Variation
Submission Category:	Type II
Submission Complexity:	Standard
EU Procedure Number (if applicable):	UK/H/5784/001/II/002

Reason:
To register a change to the product information. Sections 4.1, 4.2, 4.3, 4.4, 5.2 and 6.6 of the Summary of Product Characteristics (SmPC), the Patient Information Leaflet (PIL) and labelling have been updated. Some Quality Review of Documents (QRD) template changes have also been made to the PIL:

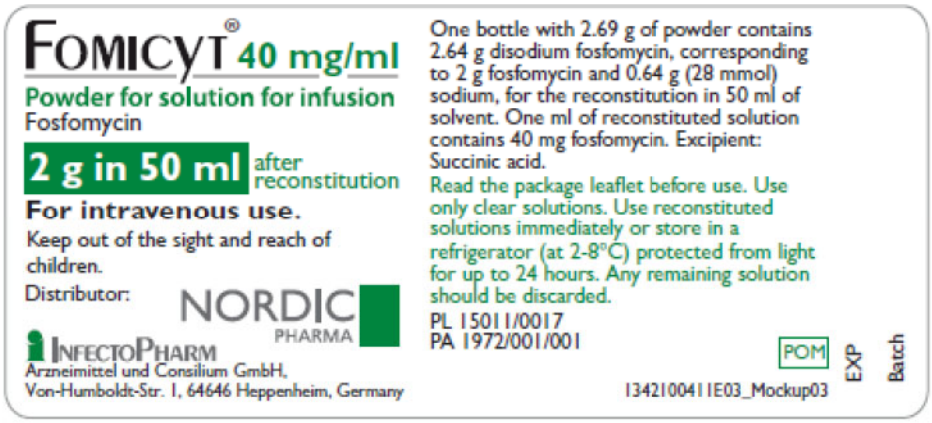
Supporting Evidence
Revised SmPC fragments (sections), updated leaflet and updated labelling have been provided.

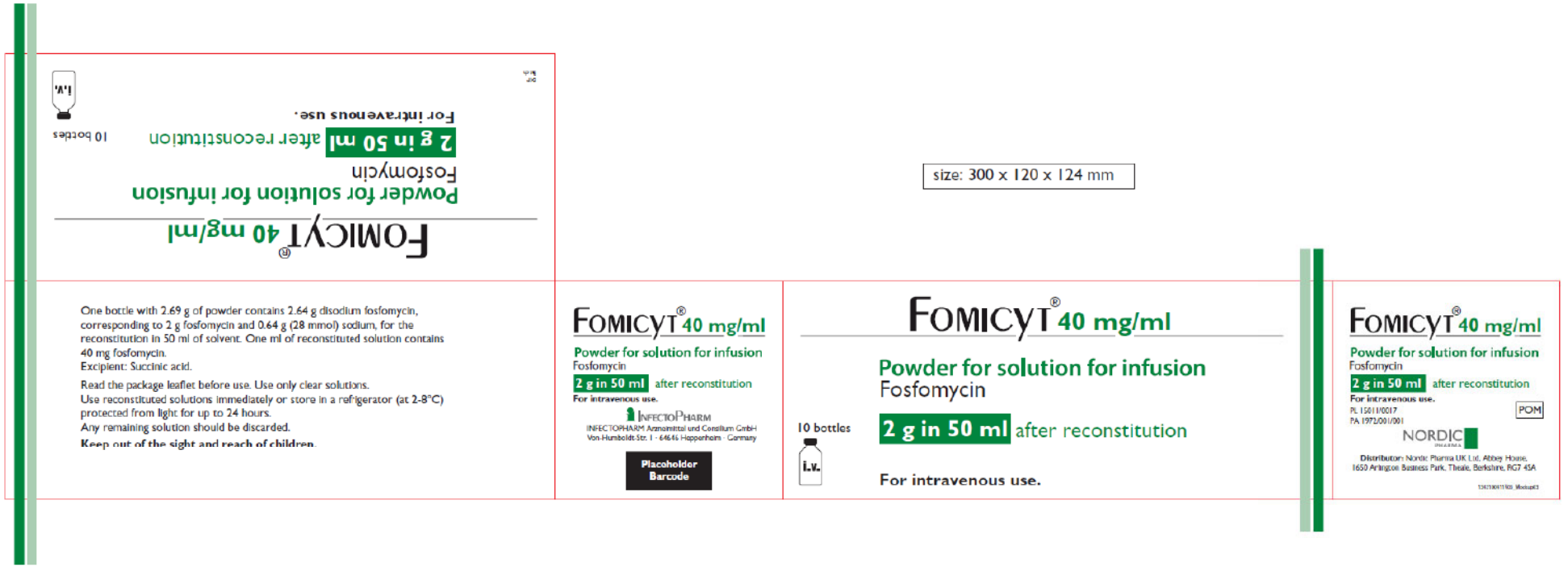
Evaluation
The updated sections of the SmPC and PIL are acceptable. The revised lavbelling is also acceptable.

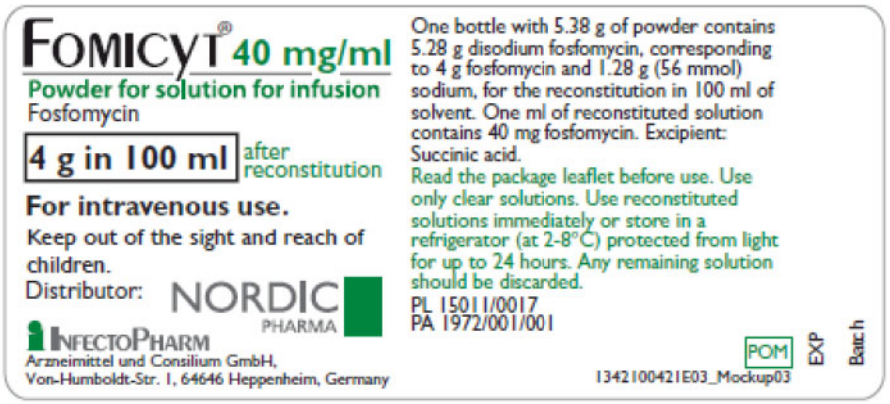
Conclusion
The updated sections of the SmPC, the revised PIL and labelling are satisfactory and there are no objections to approval.

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The current approved labelling is as below:




FOMICYT® 40 mg/ml
Powder for solution for infusion
Fosfomycin
2 g in 50 ml after reconstitution
For intravenous use.
10 bottles
i.v.
One bottle with 2.69 g of powder contains 2.64 g disodium fosfomycin, corresponding to 2 g fosfomycin and 0.64 g (28 mmol) sodium, for the reconstitution in 50 ml of solvent. One ml of reconstituted solution contains 40 mg fosfomycin.
Excipient: Succinic acid.
Read the package leaflet before use. Use only clear solutions.
Use reconstituted solutions immediately or store in a refrigerator (at 2-8°C) protected from light for up to 24 hours.
Any remaining solution should be discarded.
Keep out of the sight and reach of children.
INFECTOPHARM
INFECTOPHARM Arzneimittel und Consilium GmbH
Von-Humboldt-Str. 1 · 64646 Heppenheim · Germany
Placeholder Barcode
size: 300 x 120 x 124 mm
FOMICYT® 40 mg/ml
Powder for solution for infusion
Fosfomycin
2 g in 50 ml after reconstitution
For intravenous use.
10 bottles
i.v.
FOMICYT® 40 mg/ml
Powder for solution for infusion
Fosfomycin
2 g in 50 ml after reconstitution
For intravenous use.
PL 15011/0017
PA 1972/001/001
POM
NORDIC
Distributor: Nordic Pharma UK Ltd, Abbey House, 1650 Arlington Business Park, Theale, Berkshire, RG7 4SA



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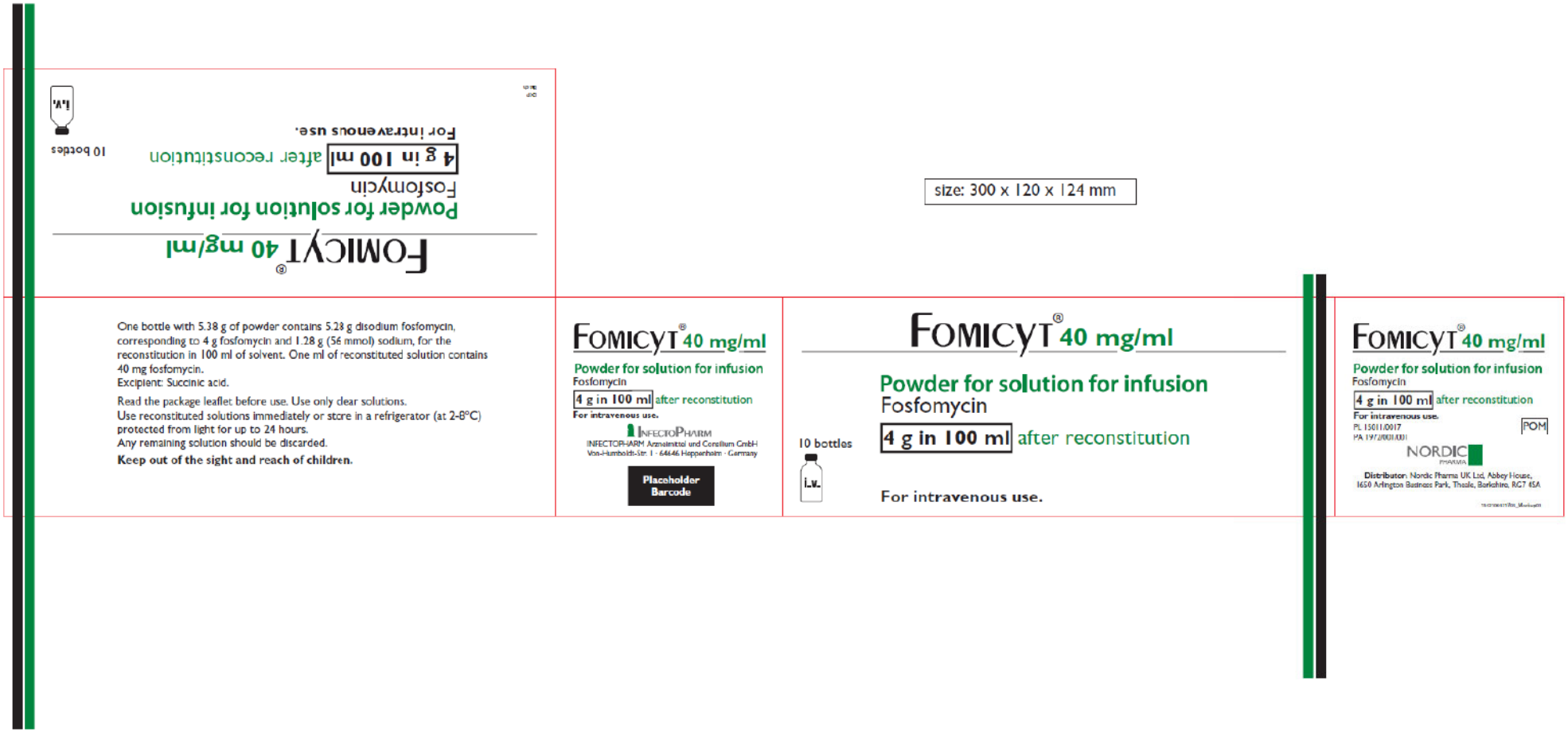
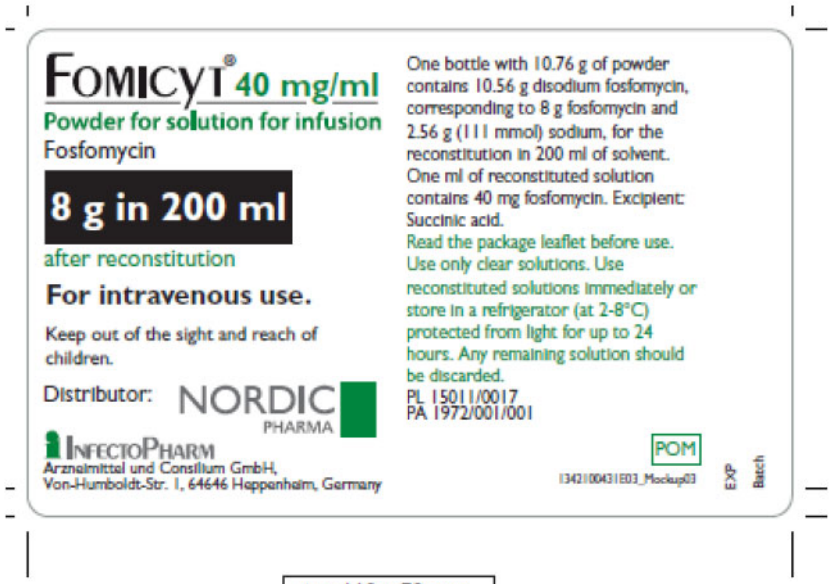
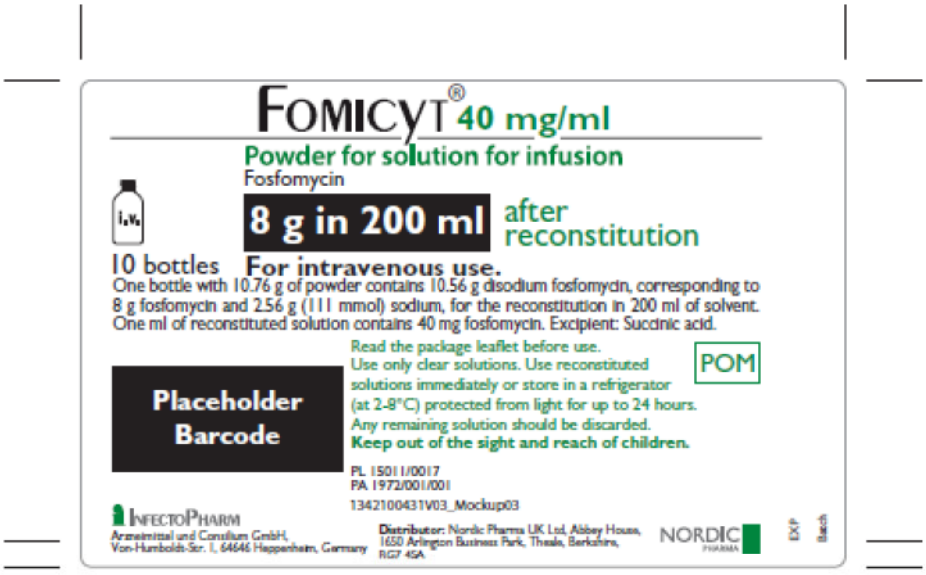

FOMICYT® 40 mg/ml
Powder for solution for infusion
Fosfomycin
4 g in 100 ml after reconstitution
For intravenous use.
10 bottles
i.v.
One bottle with 5.38 g of powder contains 5.28 g disodium fosfomycin, corresponding to 4 g fosfomycin and 1.28 g (56 mmol) sodium, for the reconstitution in 100 ml of solvent. One ml of reconstituted solution contains 40 mg fosfomycin.
Excipient: Succinic acid.
Read the package leaflet before use. Use only clear solutions.
Use reconstituted solutions immediately or store in a refrigerator (at 2-8°C) protected from light for up to 24 hours.
Any remaining solution should be discarded.
Keep out of the sight and reach of children.
INFECTOPHARM
INFECTOPHARM Arzneimittel und Consilium GmbH
Von-Humboldt-Str. 1 · 64646 Heppenheim · Germany
Placeholder Barcode
size: 300 x 120 x 124 mm
10 bottles
i.v.
For intravenous use.
POM
PL 15011/0017
NORDIC PHARMA
Distributor: Nordic Pharma UK Ltd, Abbey House, 1650 Arlington Business Park, Theale, Berkshire, RG7 4SA



size: 110 x 70 mm



size: 110 x 70 mm

Decision – Approved 09 June 2017.