

Importation of UK-labelled FOMICYT (Fosfomycin IV) due to the anticipated shortage of Canadian-authorized IVOZFO™ (Fosfomycin for Injection)

Verity Pharmaceuticals Inc.
2560 Matheson Blvd. E., Suite 220
Mississauga, ON, Canada,
L4W 4Y9

December 21, 2023

Dear

Group Purchasing Organizations,

There is an anticipated critical shortage of IVOZFO™ (Fosfomycin for Injection) in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of UK-labelled FOMICYT® (Fosfomycin IV), with English-only labels, by Verity Pharmaceuticals Inc.

Health Canada has accepted the addition of this drug product to the [List of drugs for exceptional importation and sale](#).

In Canada, IVOZFO™ (Fosfomycin for Injection) is a prescription drug product indicated for the treatment of the following infections in adults and children, including neonates:

- Bacterial meningitis
- Bone and joint infections
- Complicated intra-abdominal infections
- Complicated skin and soft tissue infections
- Complicated urinary tract infections
- Hospital-acquired pneumonia, including ventilator-associated pneumonia
- Infective endocarditis
- Bacteremia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Fosfomycin for Injection 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 UK-labelled product is available as 4g powder in vials to be reconstituted to a total volume of 120 mL and, has the **identical active ingredient, strength (4 g/vial), dosage form (powder for solution), route of administration (intravenous), and non-medicinal ingredient (succinic acid)** as the Canadian-authorized product, but **differs with respect to the brand name (FOMICYT® for the UK-labelled product and IVOZFO for the Canadian-authorized product) and in-use period for the final diluted solution** (i.e., the reconstituted and diluted drug product can be **stored for up to 24 hours** for the UK-labelled product versus up to 48 hours for the Canadian-authorized product).

With the exception of the in-use period for the final diluted solution, healthcare professionals should refer to the Canadian Product Monograph for IVOZFO™ available in English and French on the Health Canada [Drug Product Database](#) for information on the proper use of the product, including the indications, contraindications, dosage and administration, warnings and precautions, adverse reactions, drug interactions, storage conditions, and handling instructions.

Healthcare professionals are advised to follow the 24 hour in-use period for the final diluted solution of FOMICYT® as indicated in the UK Summary of Product Characteristics, which is available for reference in English at [IVOZFO availability](#).

Information on the imported product


Brand name	Dosage form, strength and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/Importer in Canada
FOMICYT®	Powder for solution, 4 g/vial fosfomycin, Intravenous	Powder for solution for infusion; 4 g in 100 mL. Available in cartons of 10 x 30 mL clear glass vials.	United Kingdom, Medicines and Healthcare products Regulatory Agency, PL15011/0017, PA1972/001/001	INFECTOPHARM Arzneimittel und Consilium GmbH, Germany Distributor: Kent Pharmaceuticals Ltd., United Kingdom	Verity Pharmaceuticals Inc. 2560 Matheson Blvd. East, Suite 220, Mississauga, Ontario, Canada, L4W 4Y9 Phone: (416) 800-7771

Images of the UK-labelled product can be found in the Appendix and at [IVOZFO availability](#).



Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the UK-labelled product may differ from IVOZFO™ marketed in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The UK-labelled product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product to be dispensed and administered to be properly identified.

	UPC CODES	BARCODE
IVOZFO™	[10628504817022]	
FOMICYT®	[42600020520971]	

Reporting adverse drug reactions

Adverse drug reactions associated with the use of **FOMICYT®** should be reported to Verity Pharmaceuticals Inc. at: 2560 Matheson Blvd. East, Suite 220, Mississauga, Ontario, Canada, L4W 4Y9, Phone: (416) 800-7771 Email: pharmacovigilance@veritypharma.com or to [Health Canada](#) or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about the UK-labelled **FOMICYT®**, please contact Verity Pharmaceuticals Inc. at: 2560 Matheson Blvd. East, Suite 220, Mississauga, Ontario, Canada, L4W 4Y9, Phone: (416) 800-7771, Email: info@veritypharma.com.

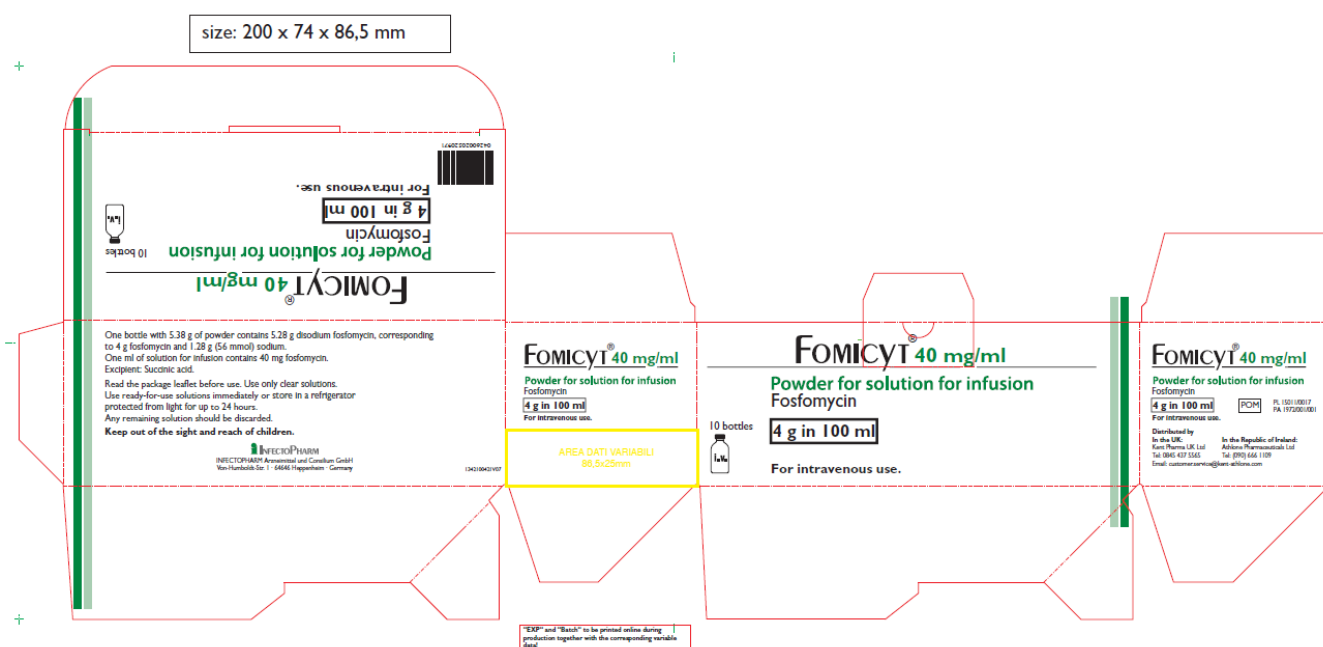
Appendix

UK-labelled FOMICYT® in bottle packaging



UK-labelled FOMICYT® outer and inner labels

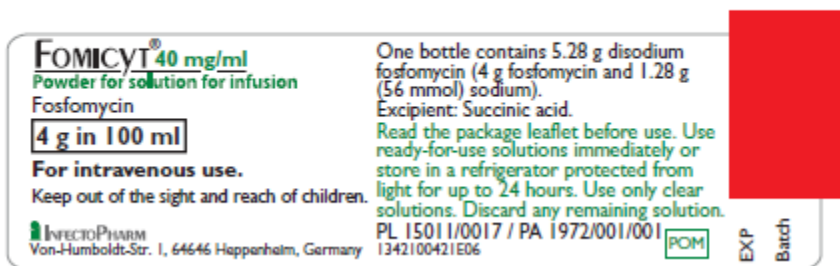
FS-Fomycin 40mg/ml, 4g UK	■ INFECTOPHARM black 70%	Pantone 356 C 30%
size: 200 x 74 x 84,5 mm	carton Fomicyt 4 g, Pharmatex, YKo/MUH	Pantone 356 C
colour: black / Pant 356 C	Fontsize: 8-18 Pt	■ Pantone 356 C ■ black ■ Pantone 280 CV
Id.-Nr.: 1342100421V06	FOMICYT® 40 mg/ml	■ varnish free area ■ die-cut





E-Fomicyt, 4g (Vial label), uk/ie	■ INFECTOPHARM Schwarz 70%	■ PMS 356 C
size: 90 x 26 mm	Gill sans 6 Pt / Pharmatex / YKo/MUH	■ black
colours: black/ PMS 356 C	FOMICYT 40 mg/ml	■ Vanish free area
Id.-Nr.: 1342100421E05		

Size 90x26 mm



Outer Label - Description

Fomicyt 40mg/ml

Powder for solution for infusion

Fosfomycin

4 g in 100 ml

For intravenous use.

New reconstitution procedure

Read the package leaflet before use

10 bottles

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.

One ml of solution for infusion contains 40 mg fosfomycin.

Excipient: Succinic acid.

Read the package leaflet before use. Use only clear solutions.

Use ready-for-use solutions immediately or store in a refrigerator protected from light for up to 24 hours.

Any remaining solution should be discarded.

Keep out of the sight and reach of children.

INFECTOPHARM Arzneimittel und Consilium GmbH Von-Humboldt-Str. 1 64646 Heppenheim Germany

Distributor in the UK

Kent Pharmaceuticals

Limited, Repton Road,

Measham, DE12 7DT, U.K.



Inner Labels - Description

Fomycit 40mg/ml

Powder for solution for infusion

Fosfomycin

4 g in 100 ml

For intravenous use.

Keep out of sight and reach of children.

Distributor in the UK: Kent Pharmaceuticals Ltd

Von-Humboldt-Str. 1, 64646 Heppenheim, Germany

One bottle contains 5.28 g disodium fosfomycin (4 g fosfomycin and 1.28 g (56 mmol) sodium). Excipient: Succinic acid.

Read the package leaflet before use. Use ready-for-use solutions immediately or store in a refrigerator protected from light for up to 24 hours. Use only clear solutions. Discard any remaining solution.
