Exceptional Importation of UK-Authorized Glucose (Dextrose) Intravenous Infusion 50% w/v in 50 mL Vials Due to the Current Shortage of Canadian-Authorized Dextrose Injection

Juno Pharmaceuticals Corp.
402-2233 Argentia Road,
Mississauga, Ontario, Canada
L5N 2X7

November 20, 2023

Dear hospitals, wholesalers, pharmacists and healthcare professional associations:

There is a critical shortage of Dextrose (otherwise known as Glucose) Injection (500 mg/mL) in Canada.

In order to help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of UK-authorized Glucose Intravenous Infusion BP 50% w/v, with English only labels, by Juno Pharmaceuticals Corp., and has added this product to the List of Drugs for Exceptional Importation and Sale (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html).

The UK-authorized Glucose Intravenous Infusion BP 50% w/v is available in 50 mL clear glass vials and contains 500 mg/mL glucose (anhydrous), hydrochloric acid for pH adjustment and water.

In Canada, Dextrose Injection (500 mg/mL) is indicated for in the treatment of insulin hypoglycemia (hyperinsulinism or insulin shock) to restore blood glucose levels. The solution is also indicated after dilution, for slow intravenous infusion as a source of carbohydrate calories in patients whose oral intake is restricted or inadequate to maintain nutritional requirements.

The UK-authorized product and the Canadian-marketed products have the **same active ingredient, strength (500 mg/mL), dosage form (hypertonic solution), and route of administration (intravenous infusion)**; however, there are **differences in the nomenclature used for the active ingredient**. "Glucose" is used in the UK product labelling, whereas "Dextrose" is used in the labelling of the Canadian-marketed products. **While the nomenclature of the active ingredient is different, glucose and dextrose are identical chemical substances.**

There are also differences in the approved indications; however, **the UK-authorized Glucose Intravenous Infusion BP 50% w/v can be used for the same indications as the Canadian-marketed Dextrose Injection (500 mg/mL) products**.

For proper use of the UK product, and for information on the indications, contraindications, warnings and precautions, adverse reactions, dosing and administration, and storage, healthcare professionals should refer to the Canadian Prescribing Information for marketed Dextrose Injection (500 mg/mL) products available in English and French on the Health Canada Drug Product Database (https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=100647**).**

Dextrose 500 mg/mL (Glucose 50%) is considered a high-alert medication by the Institute for Safe Medication Practices (ISMP). It is important to note that the warning message on the Canadian product inner & outer labels to alert users to the **"hypertonic solution/slow rate of IV administration"** is **not** found on the UK-authorized product but should be adhered to.

Information on the imported product

Brand name	Dosage form, strength and route of administration	Product packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Glucose Intravenous Infusion BP 50% w/v	Solution, 500 mg/mL glucose (anhydrous), for intravenous infusion	50 mL clear glass vial with a rubber stopper and an aluminum and light green plastic flip-off cap. Available in carton packs of 25 vials.	United Kingdom PL 01502/00005R	Hameln Pharma Ltd., United Kingdom	Juno Pharmaceuticals Corp., Canada

Information about the UK-authorized Glucose Intravenous Infusion 50% w/v for healthcare professionals is available for reference in English only at the following link:

https://www.medicines.org.uk/emc/product/6266/smpc

Images of the UK-authorized product can be found in the Appendix below. Healthcare professionals are advised that other aspects of the inner and outer labels and packaging of the UK-authorized drug product may differ from marketed Dextrose Injection (500 mg/mL) products in Canada. **Proper selection of the intended drug product must be verified to avoid confusion with other drug products and prevent medication errors.**

The UK-authorized 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 being dispensed and administered to be properly identified.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of UK-authorized Glucose Intravenous Infusion 50% w/v should be reported to Juno Pharmaceuticals Corp. by calling 1-855-819-0505 or 1-866-663-1747 or to Health Canada at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about UK-authorized Glucose Intravenous Infusion 50% w/v, please contact Juno Pharmaceuticals Corp., 402-2233 Argentia Road, Mississauga, ON, L5N 2X7.

Appendix

1. **Images of UK-authorized Glucose Intravenous Infusion BP 50% w/v**

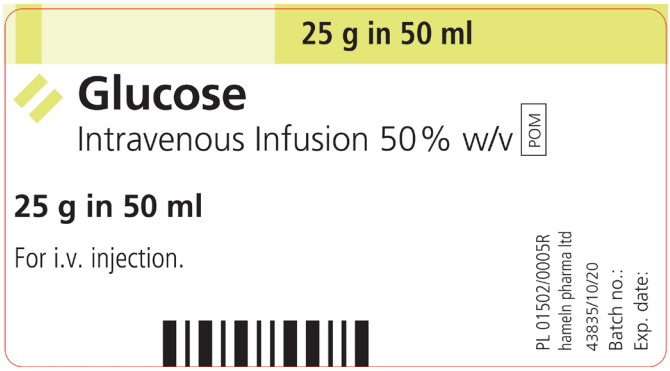
Sincerely,

Paul J. Varady
VP, Quality and Regulatory Affairs
Juno Pharmaceuticals Canada

Appendix - Images of UK-Authorized Glucose Intravenous Infusion 50% w/v

Product Photos

UK Vial Label



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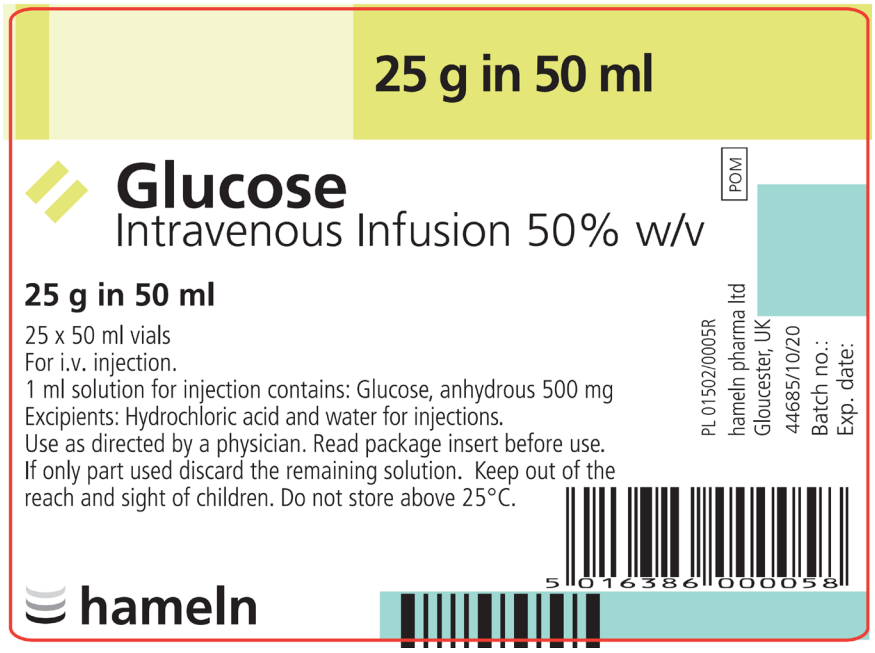
Plain text UK vial label

Left Panel
25 g in 50 ml Glucose Intravenous Infusion 50% w/v 25 g in 50 ml For i.v. injection.
Right Panel Text oriented vertically
PL 01502/0005R, in a box “POM” hameln pharma ltd 43835/10/20 Batch no.: Exp. Date:

UK Carton Label



Plain text UK carton label

Left Panel
25 g in 50 ml Glucose Intravenous Infusion 50% w/v

25 g in 50 ml 25 x 50 ml vials For i.v. injection. 1 ml solution for injection contains: Glucose, anhydrous 500 mg Excipients: Hydrochloric acid and water for injections. Use as directed by a physician. Read package insert before use. If only part used discard the remaining solution. Keep out of the reach and sight of children. Do not store above 25°C. hameln corporate logo right-hand justified barcode number 5016386000058
Right Panel Text oriented vertically
PL 01502/0005R hameln pharma ltd, right hand justified in a box “POM” Gloucester, UK 44685/10/20 Batch no.: Exp. Date: