



Amphastar Pharmaceuticals Inc.
11570 6th Street
Rancho Cucamonga
California, 91730
USA

June 28, 2023

Re: Importation of US-labelled Glucagon Emergency Kit for Low Blood Sugar (Glucagon for Injection) due to the anticipated shortage of the Canadian-authorized Glucagon

Dear Healthcare Professional:

There is an anticipated critical shortage of Glucagon for Injection in Canada. To help manage the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Amphastar Pharmaceuticals' US labelled **Glucagon Emergency Kit for Low Blood Sugar** (Glucagon for Injection) with English labels.

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

In Canada, Glucagon is indicated for the emergency treatment of severe hypoglycemia in patients treated with insulin when unconsciousness precludes oral carbohydrates, and as a diagnostic aid in the radiologic examination of the stomach, duodenum, small bowel, and colon when diminished intestinal motility would be advantageous.

IMPORTANT - Amphastar's Glucagon for Injection is NOT considered equivalent to Eli Lilly's Canadian marketed Glucagon (DIN 02243297). Please follow the US labelling when using Amphastar's Glucagon for Injection, since there is no equivalent Canadian labelling available.

Glucagon for Injection (synthetic origin) is a polypeptide hormone identical to human glucagon that increases blood glucose concentration by converting liver glycogen to glucose, and relaxes smooth muscle of the gastrointestinal tract.

Indications

Glucagon for Injection is indicated for the following:

For the treatment of severe hypoglycemia:

Glucagon is indicated as a treatment for severe hypoglycemia (low blood sugar) which may occur in patients with diabetes mellitus.

Because patients with Type 1 diabetes may have less of an increase in blood glucose levels compared with a stable Type 2 patient, supplementary carbohydrate should be given as soon as possible, especially to a pediatric patient.

Glucagon is effective in treating hypoglycemia only if sufficient liver glycogen is present. Hypoglycemia in states of starvation, adrenal insufficiency or chronic hypoglycemia should not be treated with glucagon.

For use as a diagnostic aid:

Glucagon is indicated as a diagnostic aid in the radiologic examination of the stomach, duodenum, small bowel, and colon when diminished intestinal motility would be advantageous.

Glucagon is as effective for this examination as are the anticholinergic drugs. However, as use of glucagon in combination with anticholinergic drugs may result in increased side effects, the use of glucagon in combination with anticholinergic drugs is not recommended.

Contraindications:

Glucagon is contraindicated in patients with known hypersensitivity to it, or in patients with known pheochromocytoma.

Warnings and Precautions:

Glucagon should be administered cautiously to patients with a history suggestive of insulinoma, pheochromocytoma, or both.

Adverse reactions:

Side effects may include nausea and vomiting, a temporary increase in heart rate, and allergic reactions to glucagon or to one of the inactive ingredients in glucagon.

Generalized allergic reactions, including urticaria, respiratory distress, and hypotension, have been reported in patients who received glucagon by injection.

Necrolytic migratory erythema (NME), a skin rash commonly associated with glucagonomas (glucagon producing tumors) has been reported following continuous glucagon infusion.

Dosage and Administration:

1mg subcutaneously, intramuscularly, or intravenously for adults and pediatric patients weighing more than 20 kg. For smaller pediatric patients, see prescribing information.

The diluent is provided for use only in the preparation of glucagon for parenteral injection and for no other use.

Glucagon should not be used at concentrations greater than 1 mg/mL

The product is intended for single use only.

Reconstituted glucagon solutions should be used only if they are clear and of a water-like consistency.

Storage

Store the kit at controlled room temperature between 20° to 25°C (68° to 77°F) before mixing glucagon with the diluent.

After Reconstitution - Glucagon for Injection should be used immediately. **Discard any unused portion.**

Information on the imported product (US labeled)

Brand name	Product Description and Route of Administration	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Glucagon Emergency Kit for Low Blood Sugar (Glucagon for Injection)	Kit contains: 1 mg glucagon for injection (as a sterile, lyophilized white to off-white powder) in a single-dose vial & 1 mL of diluent for glucagon in a prefilled syringe. For intramuscular, subcutaneous or intravenous injection.	United States Food and Drug Administration, National Drug Code (NDC): #0548-5850-00	Amphastar Pharmaceuticals Inc. 11570 6 th Street, Rancho Cucamonga California 91730 USA	Amphastar Pharmaceuticals Inc 2000 Ellesmere Rd, Unit 16, Scarborough, ON M1H 2W4 Canada

The most current U.S. labeling in distribution for Glucagon for Injection, USP, 1 mg/vial, packaged in an emergency kit is available in English only on the DailyMed web site:
<https://www.accessdata.fda.gov/spl/data/7b1b15a9-4632-4749-b4ad-95dd0c5d3966/7b1b15a9-4632-4749-b4ad-95dd0c5d3966.xml>.

Full digital copies (English and French-translation) of the US-labelled Glucagon for Injection Package Insert can be accessed from the links below:

Glucagon for Injection (EN):

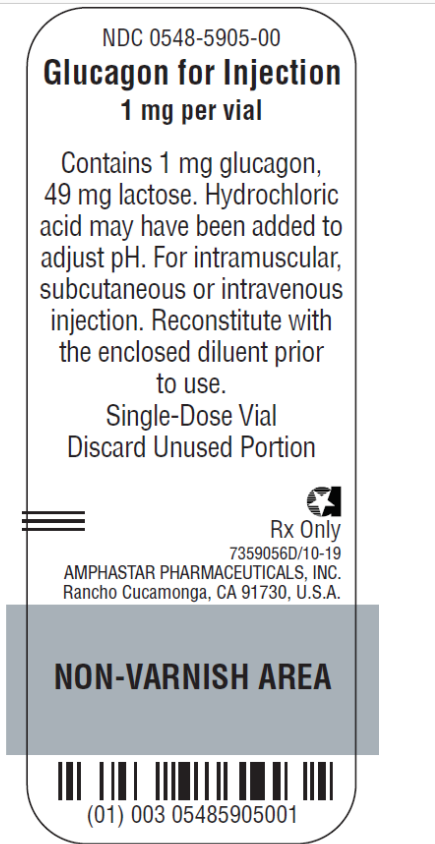
<https://amphastar.com/glucagon-2.html>

Glucagon for Injection (FR):

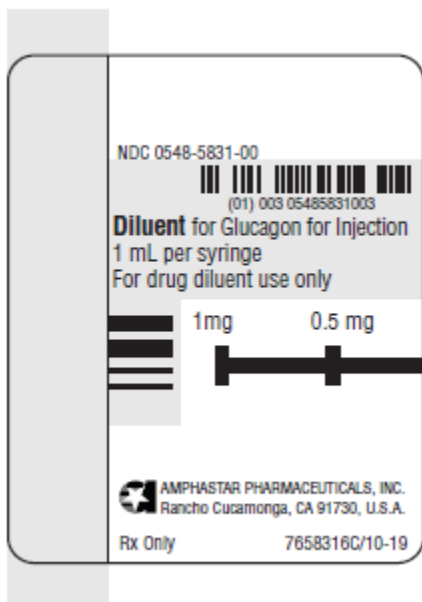
<https://amphastar.com/glucagon-2.html>

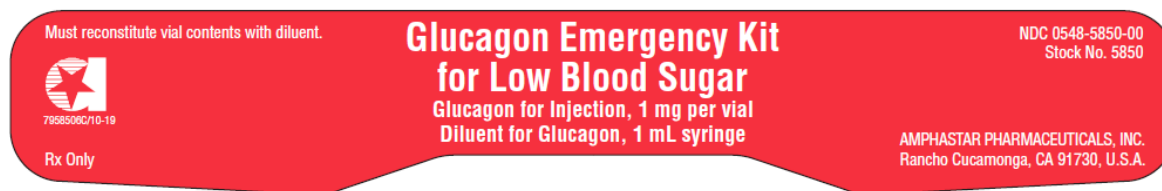
Images of the US-labelled Glucagon for Injection :

Glucagon Inner Label



Diluent Inner Label



Outer Label

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

The US-labelled Glucagon for Injection does not have a 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 Glucagon for Injection should be reported to Amphastar Pharmaceuticals, Inc. by calling toll-free 1-800-423-4136, 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 US-labelled Glucagon for Injection, Amphastar Pharmaceuticals Inc. may be contacted at 1-800-423-4136 or 1-909-980-9484.

To place an order for Glucagon for Injection, U.S. UPC: 003 05485850004, please call: Lynden International Logistics at 1-800-268-4937.

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