

# Glucagon

## Emergency Kit

The FDA-approved Glucagon Emergency Kit from Fresenius Kabi is a cost-effective alternative to emergency solutions you have trusted for years.



**FRESENIUS  
KABI**

caring for life

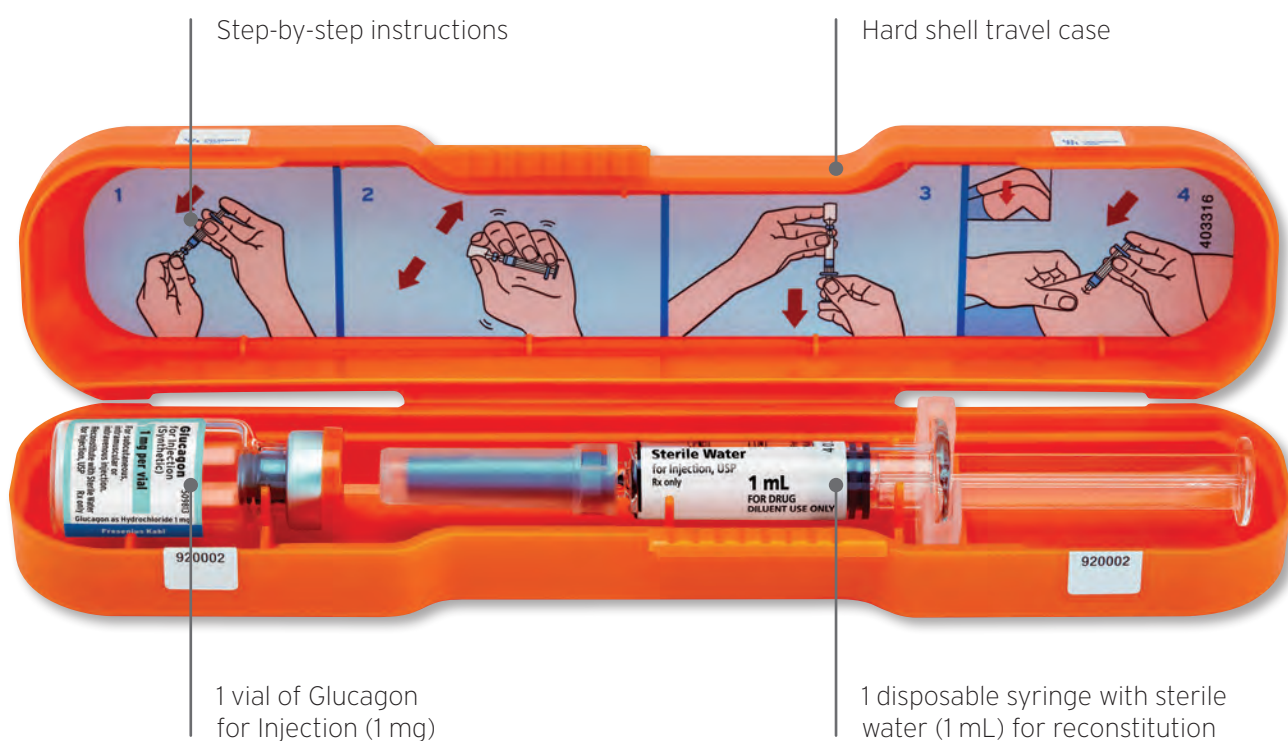
# Glucagon Emergency Kit

The FDA-approved Glucagon Emergency Kit provides flexibility and choice for your patients. Fresenius Kabi's Glucagon Emergency Kit is a cost-effective alternative that meets the same quality standards as other products on the market.

## Be Confident

### Now a Cost-Effective Solution for a Known and Trusted Treatment of Severe Hypoglycemia

For patients with diabetes, a hypoglycemic episode can occur anywhere, anytime. At home, school or work, the Glucagon Emergency Kit is convenient and easy to use. This injection is administered under the skin to quickly treat patients with diabetes who experience unexpected episodes of severe hypoglycemia.



Please see Important Safety Information on the following page and accompanying package insert for full prescribing information.



Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. We are a leading provider of generic medications with a 100-year history of delivering innovative therapies that are safe, efficient and affordable. That's how we bring **confidence within reach.**

# A Cost-Effective Alternative from an Experienced, Reliable Supplier



## Glucagon for Injection

- Fresenius Kabi's Glucagon for Injection followed the 505(b)(2) NDA regulatory pathway due to the difference in manufacturing of a synthetic versus recombinant active pharmaceutical ingredient (API).
- Fresenius Kabi completed a bioequivalence (BE) study that concluded Glucagon for Injection was bioequivalent to GlucaGen®.<sup>1</sup>

## Bioequivalence Study Description for Glucagon for Injection

A randomized, single-dose, single-blind, 2-treatment, 4-period, replicate crossover study was conducted to determine the bioequivalence of Glucagon for Injection to GlucaGen® after subcutaneous injection in 32 normal, healthy subjects. During the course of the study, subjects received either 1 mg Glucagon for Injection or 1 mg GlucaGen® in each period. Baseline corrected pharmacokinetic and pharmacodynamic parameters were assessed in 27 subjects.

The results of the study demonstrated that Fresenius Kabi's Glucagon for Injection produced plasma glucagon concentrations and baseline adjusted blood glucose concentrations similar to those achieved after the administration of GlucaGen®.

A total of 185 treatment emergent adverse events were experienced by subjects who received Glucagon for Injection (n=31) and GlucaGen® (n=29). The most frequently reported adverse events for Glucagon for Injection and GlucaGen®, respectively, were injection site swelling (58% and 55%) and injection site erythema (55% and 66%). There were no deaths or serious adverse events in this study.

The study concluded that Fresenius Kabi's Glucagon for Injection demonstrated pharmacokinetic and pharmacodynamic bioequivalence to GlucaGen®.

1. Data on file. Bioequivalence of a test formulation of Glucagon for SC injection compared to Glucagon for Injection under fasted conditions. Fresenius Kabi USA LLC.



Please visit [GlucagonEmergencyKit.com](http://GlucagonEmergencyKit.com) for more information.



Consider prescribing multiple kits to help your patients and their caregivers be prepared – one kit for home use, and one kit for school or office.

## Ordering Information

Glucagon Emergency Kit may be ordered from your pharmaceutical wholesaler. It is also available at pharmacy retailers and requires a prescription.

NDC Number: 63323-582-82

For more information please visit [GlucagonEmergencyKit.com](http://GlucagonEmergencyKit.com)

### INDICATION AND USAGE

Glucagon for Injection is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes.

### IMPORTANT SAFETY INFORMATION

Glucagon for Injection is contraindicated in patients with pheochromocytoma, insulinoma, or a known hypersensitivity to glucagon or any of the excipients.

**Catecholamine Release in Patients with Pheochromocytoma:** Glucagon for Injection is contraindicated in patients with pheochromocytoma because Glucagon for Injection may stimulate the release of catecholamines from the tumor.

**Hypoglycemia in Patients with Insulinoma:** In patients with insulinoma, administration may produce an initial increase in blood glucose; however, Glucagon for Injection may stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. If a patient develops symptoms of hypoglycemia after a dose of Glucagon for Injection, give glucose orally or intravenously.

**Hypersensitivity and Allergic Reactions:** Allergic reactions have been reported and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension.

**Lack of Efficacy in Patients with Decreased Hepatic Glycogen:** Glucagon for Injection is effective in treating hypoglycemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycemia may not have adequate levels of hepatic glycogen for Glucagon

for Injection to be effective. Patients with these conditions should be treated with glucose.

**Necrolytic Migratory Erythema (NME):** a skin rash, has been reported postmarketing following continuous glucagon infusion and resolved with discontinuation of the glucagon. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks.

**Most common adverse reactions (>5% or greater incidence):** Injection site swelling, injection site erythema, vomiting, nausea, decreased blood pressure, asthenia, headache, dizziness, pallor, diarrhea, and somnolence.

**To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Beta-blockers:** Patients taking beta-blockers may have a transient increase in pulse and blood pressure.

**Indomethacin:** In patients taking indomethacin Glucagon for Injection may lose its ability to raise glucose or may produce hypoglycemia.

**Warfarin:** Glucagon for Injection may increase the anticoagulant effect of warfarin.

**This Important Safety Information does not include all the information needed to use Glucagon for Injection safely and effectively. Please see accompanying package insert for full prescribing information. Full prescribing information is also available at [www.fresenius-kabi.com/us](http://www.fresenius-kabi.com/us).**