Glucagon Emergency Kit for Low Blood Sugar

PRODUCT	DELIVERY SYSTEM	UNIT SIZE	UNITS / BOX	NDC#
Glucagon Emergency Kit for Low Blood Sugar	Kit	1 mg	1	0548-5850-00

- **Generic Glucagon for Injection**
- **Bioequivalent and therapeutically equivalent to Lilly's Glucagon Emergency Kit**
- **AP Rated**
- **For the treatment of severe hypoglycemia**
- **For use as a diagnostic aid**

For more information,
PLEASE CALL 1-800-423-4136

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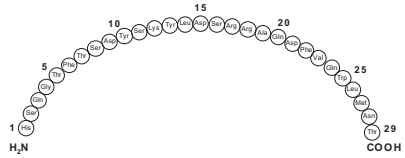
Please see reverse for important safety information for Glucagon Emergency Kit for Low Blood Sugar

Rx Only
01/21
01-025-01

Glucagon Emergency Kit for Low Blood Sugar

INFORMATION FOR THE PHYSICIAN
GLUCAGON FOR INJECTION

DESCRIPTION
Glucagon for Injection (synthetic origin) is a polypeptide hormone identical to human glucagon that increases blood glucose and relaxes smooth muscle of the gastrointestinal tract. Glucagon is produced by solid state peptide synthesis and is highly purified.
Glucagon is a single-chain polypeptide that contains 29 amino acid residues and has a molecular weight of 3483.
The empirical formula is $C_{153}H_{225}SN_{43}O_{49}S$. The primary sequence of glucagon is shown below.



Crystalline glucagon (synthetic origin) is a white to off-white powder. It is relatively insoluble in water but is soluble at a pH of less than 3 or more than 9.5.

Glucagon is available for use intravenously, intramuscularly, or subcutaneously in a kit that contains a vial of sterile glucagon and a syringe of sterile diluent. The vial contains 1 mg of glucagon and 49 mg of lactose. Hydrochloric acid may have been added during manufacture to adjust the pH of the glucagon. One International Unit of glucagon is equivalent to 1 mg of glucagon.[1] The diluent syringe contains 12 mg/mL of glycerin, Water For Injection, and hydrochloric acid.

CLINICAL PHARMACOLOGY
Glucagon increases blood glucose concentration and is used in the treatment of severe hypoglycemia. Glucagon acts only on liver glycogen, converting it to glucose.

Glucagon administered through a parenteral route relaxes smooth muscle of the stomach, duodenum, small bowel, and colon.

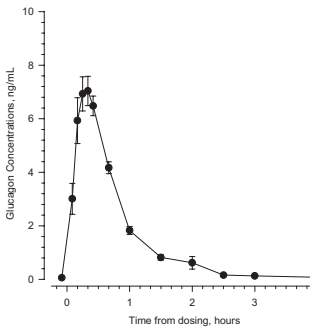
Pharmacokinetics
Glucagon has been studied following intramuscular, subcutaneous, and intravenous administration in adult volunteers. Administration of the intravenous glucagon showed dose proportionality of the pharmacokinetics between 0.25 and 2.0 mg. Calculations from a 1 mg dose showed a small volume of distribution (mean, 0.25 L/kg) and a moderate clearance (mean, 13.5 mL/min/kg). The half-life was short, ranging from 8 to 18 minutes.

Maximum plasma concentrations of 7.9 ng/mL were achieved approximately 20 minutes after subcutaneous administration (see Figure 1A). With intramuscular dosing, maximum plasma concentrations of 6.9 ng/mL were attained approximately 13 minutes after dosing. Glucagon is extensively degraded in liver, kidney, and plasma. Urinary excretion of intact glucagon has not been measured.

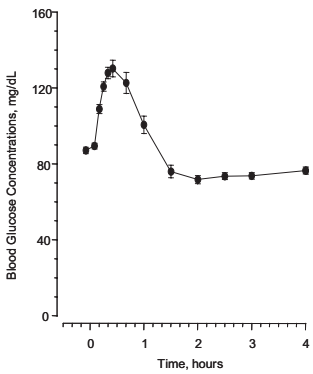
Pharmacodynamics
In a study of 25 volunteers, a subcutaneous dose of 1 mg glucagon resulted in a mean peak glucose concentration of 136 mg/dL 30 minutes after injection (see Figure 1B). Similarly, following intramuscular injection, the mean peak glucose level was 138 mg/dL, which occurred at 26 minutes after injection. No difference in maximum blood glucose concentration between animal-sourced and rDNA glucagon was observed after subcutaneous and intramuscular injection.

Figure 1
Mean (± SE) serum glucagon and blood glucose levels after subcutaneous injection of glucagon (1mg) in 25 normal volunteers

A



B



INDICATIONS AND USAGE
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.

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
Glucagon should be administered cautiously to patients with a history suggestive of insulinoma, pheochromocytoma, or both. In patients with insulinoma, intravenous administration of glucagon may produce an initial increase in blood glucose; however, because of glucagon's hyperglycemic effect the insulinoma may release insulin and cause subsequent hypoglycemia. A patient developing symptoms of hypoglycemia after a dose of glucagon should be given glucose orally, intravenously, or by gavage, whichever is most appropriate.

Exogenous glucagon also stimulates the release of catecholamines. In the presence of pheochromocytoma, glucagon can cause the tumor to release catecholamines, which may result in a sudden and marked increase in blood pressure. If a patient develops a sudden increase in blood pressure, 5 to 10 mg of phentolamine mesylate may be administered intravenously in an attempt to control the blood pressure. 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) and characterized by scaly, pruritic erythematous plaques, bullae, and erosions, has been reported postmarketing following continuous glucagon infusion. NME lesions may affect the face, groin, perineum and legs or be more widespread. In the reported cases NME resolved with discontinuation of the glucagon, and treatment with corticosteroids was not effective. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks.

PRECAUTIONS
General
Glucagon is effective in treating hypoglycemia only if sufficient liver glycogen is present. Because glucagon is of little or no help in states of starvation, adrenal insufficiency, or chronic hypoglycemia, hypoglycemia in these conditions should be treated with glucose.

Information for Patients
Refer patients and family members to the attached Information for the User for instructions describing the method of preparing and injecting glucagon. Advise the patient and family members to become familiar with the technique of preparing glucagon before an emergency arises. Instruct patients to use 1 mg for adults and ½ the adult dose (0.5 mg) for pediatric patients weighing less than 44 lb (20 kg).
Patients and family members should be informed of the following measures to prevent hypoglycemic reactions due to insulin:

1. Reasonable uniformity from day to day with regard to diet, insulin, and exercise.
2. Careful adjustment of the insulin program so that the type (or types) of insulin, dose, and time (or times) of administration are suited to the individual patient.
3. Frequent testing of the blood or urine for glucose so that a change in insulin requirements can be foreseen.
4. Routine carrying of sugar, candy, or other readily absorbable carbohydrate by the patient so that it may be taken at the first warning of an oncoming reaction.

To prevent severe hypoglycemia, patients and family members should be informed of the symptoms of mild hypoglycemia and how to treat it appropriately.

Family members should be informed to arouse the patient as quickly as possible because prolonged hypoglycemia may result in damage to the central nervous system. Glucagon or intravenous glucose should awaken the patient sufficiently so that oral carbohydrates may be taken.

Patients should be advised to inform their physician when hypoglycemic reactions occur so that the treatment regimen may be adjusted if necessary.

Laboratory Tests
Blood glucose determinations should be obtained to follow the patient with hypoglycemia until patient is asymptomatic.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Because glucagon is usually given in a single dose and has a very short half-life, no studies have been If you experience any other reactions which are likely to have been caused by glucagon, please contact your doctor.

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

Glucagon that has been mixed with diluent should be used immediately. Discard any unused portion. Solutions should be clear and of a water-like consistency at time of use.

Literature revised October 2019

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