Gvoke HypoPen® (glucagon injection)

A brief introduction for healthcare professionals

The Next Generation of Gvoke®

Gvoke HypoPen®

Simple Administration.[1]
Delivered with Certainty.[1]

The first autoinjector for severe hypoglycemia[2,3]:

- Ready to use[3]
- Reliable method of delivery[2]
- Proven to work[3]

For the treatment of severe hypoglycemia in adult and pediatric patients with diabetes ages 2 and above.[3]

Please see Important Safety Information on last page and Full Prescribing Information here.

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Gvoke HypoPen® (glucagon injection)

Talk with your patients about why Gvoke HypoPen® might be right for them.

Ready to use[3]

- Premixed and ready to go[3]
- Certainty of a subcutaneous injection, with no visible needle[1,4]
- Anyone can use in 2 simple steps[1,2]

1

Pull red cap off.

2

Push yellow end down on skin and hold 5 seconds. Window will turn **red**.

Administer into upper arm, lower stomach, or outer thigh.

Please see Gvoke HypoPen Instructions for Use for full detailed instructions at GvokeGlucagon.com.

Reliable method of delivery[2]

Successful administration in simulated emergency situations[2]:

Gvoke HypoPen

99%

of participants (74/75) were able to successfully administer Gvoke HypoPen

Glucagon Emergency Kit

31%

of participants (5/16) were able to successfully administer a traditional glucagon emergency kit

Study Design:
The usability of Gvoke HypoPen was evaluated in a summative human factors validation study in which 45 trained and 30 untrained adolescent and adult subjects were asked to successfully prepare and administer a full dose of treatment under simulated emergency conditions.

Study Design:
The comparative usability study was conducted in which 8 trained and 8 untrained participants were asked to successfully prepare and administer a full dose of treatment under simulated emergency situations. Results from this study were used to inform the final Gvoke HypoPen Instructions for Use, which was evaluated in the summative human factors validation study.

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Proven to work[3]

Across 2 clinical trials in adults[3]:

- **99%** (152/154) of adults had their glucose levels raised to safe levels*

In a pediatric trial[3]:

- **100%** (30/30) of pediatric patients had their glucose levels raised to safe levels†
- Premeasured doses: adult (1.0 mg) and pediatric (0.5 mg)[3]

*Blood glucose >70 mg/dL or an increase of blood glucose of ≥20 mg/dL from baseline.

†Target glucose increase of ≥25 mg/dL at 30 minutes.

Gvoke was evaluated in adult patients aged 18 to 74 years with type 1 diabetes in 2 multicenter, randomized, blinded, 2-way crossover clinical trials. 154 subjects received an injection of Gvoke and 157 subjects received an injection of glucagon emergency kit; 152 subjects received both products. The comparison between groups met the prespecified noninferiority margin.

Gvoke was evaluated in a clinical trial in 31 pediatric patients with type 1 diabetes. Patients were administered insulin to induce a low normal glycemic state of <80 mg/dL. Patients aged 2 to <12 years then received a 0.5 mg dose of Gvoke. Patients aged ≥12 years received a 0.5 mg or 1.0 mg dose of Gvoke.

Established Safety[3]

- Clinical trials have proven Gvoke HypoPen is safe with no severe side effects[3]
  - >80% of the adverse reactions were mild[5]
  - Most common adverse reactions for adults were nausea (30%), vomiting (16%), injection-site edema (1 mm or greater) (7%), headache (5%)[3]
  - Most common adverse reactions for children were nausea (45%), hypoglycemia (39%), vomiting (19%), headache (7%), hyperglycemia (7%), abdominal pain (3%), injection-site discomfort (3%), injection-site reaction (3%), urticaria (3%)[3]

Sign up to be in the know at GvokeGlucagonPro.com

INDICATION AND IMPORTANT SAFETY INFORMATION

GVOKE is indicated for the treatment of severe hypoglycemia in adult and pediatric patients with diabetes ages 2 years and above.

IMPORTANT SAFETY INFORMATION

Contraindications

GVOKE is contraindicated in patients with pheochromocytoma, insulinoma, and known hypersensitivity to glucagon or to any of the excipients in GVOKE. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

Warnings and Precautions

GVOKE is contraindicated in patients with pheochromocytoma because glucagon may stimulate the release of catecholamines from the tumor. If the patient develops a dramatic increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, GVOKE administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. GVOKE is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of GVOKE, give glucose orally or intravenously.

Allergic reactions have been reported with glucagon. These include generalized rash, and in some cases, anaphylactic shock with breathing difficulties and hypotension. GVOKE is contraindicated in patients with a prior hypersensitivity reaction.

GVOKE 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 GVOKE administration to be effective. Patients with these conditions should be treated with glucose.

Necrolytic migratory erythema (NME), a skin rash commonly associated with glucagonomas 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. Glucagon administered to patients with glucagonoma may cause secondary hypoglycemia.

Adverse Reactions

Most common (≥5%) adverse reactions associated with GVOKE are nausea, vomiting, injection site edema (raised 1 mm or greater), and hypoglycemia.

Drug Interactions

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given GVOKE. In patients taking indomethacin, GVOKE may lose its ability to raise blood glucose or may even produce hypoglycemia. GVOKE may increase the anticoagulant effect of warfarin.

Please see Full Prescribing Information here.

References:
1. Gvoke HypoPen [instructions for use]. Chicago, IL: Xeris Pharmaceuticals, Inc; 2019.
2. Valentine V, Newswanger B, Prestrelski S, Andre AD, Garibaldi M. Human factors usability and validation studies of a glucagon autoinjector in a simulated severe hypoglycemia rescue situation. *Diabetes Technol Ther.* 2019;21(9):522-530. **3.** Gvoke [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc; 2019. **4.** Christiansen M, Cummins M, Prestrelski S, Junaidi MK. A phase 3 comparison of a ready-to-use liquid glucagon rescue pen to glucagon emergency kit for the symptomatic relief of severe hypoglycemia. Poster presented at: WCTD 2018; December 3-4, 2018; Vienna, Austria. **5.** Data on file.

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