



GVOKE (pronounced GEE-vok) (glucagon injection) is the first FDA-approved autoinjector for very low blood sugar that is premixed and ready to go. It is a prescription medicine used to treat very low blood sugar (severe hypoglycemia) in adults and kids with diabetes ages 2 years and above. It is available in both pediatric (0.5mg/0.1mL) and adult (1.0mg/0.2mL) doses.<sup>1</sup>

GVOKE reduces the steps to prepare and administer glucagon in the event of severe hypoglycemia, or dangerously low blood sugar levels. This innovation is designed to provide the reliability of a ready-to-use liquid glucagon while making it easier for patients or caregivers to administer quickly and simply. Studies demonstrated 100% treatment success\* in children and 99% treatment success in adults. Usability research evaluating the GVOKE PFS and GVOKE HypoPen demonstrated 99% success rates in administering a full dose of glucagon using the simple 2-step administration process.<sup>2-3</sup>

Very low blood sugar, or severe hypoglycemia, occurs when your blood sugar gets so low that you need help to bring it back up. Sometimes people with very low blood sugar may have a hard time thinking straight or controlling their body, get very tired, refuse to eat, pass out, or even have a seizure. It is an emergency situation that needs to be treated immediately.<sup>4</sup>

There are many reasons that people may be at risk for very low blood sugar:<sup>4-7</sup>

- You take insulin or sulfonylurea to help you manage your diabetes
- You exercise at an intense level
- You tend to skip meals
- You have an inconsistent schedule
- You're often stressed
- You have tight blood sugar goals
- You tend to have insulin pump problems
- You're more sensitive to insulin
- You've had very low blood sugar in the past
- You have a hard time recognizing signs that your blood sugar is low
- You've had diabetes for a long time
- You have trouble taking your medicine

The ADA Standards of Care recommends that glucagon be prescribed for everyone who has an increased risk for very low blood sugar, so it's available should it be needed.<sup>8</sup>

\*Treatment success for adults was achieved if a person's plasma glucose reached higher than 70 mg/dL or increased by at least 20 mg/dL within 30 minutes after receiving Gvoke. Treatment success for children and adolescents was achieved if a person experienced a plasma glucose increase of at least 25 mg/dL.<sup>1</sup>

## Important Safety Information

### WARNINGS

Do not use GVOKE if: you have a tumor in the gland on top of your kidneys (adrenal gland), called a pheochromocytoma. you have a tumor in your pancreas called an insulinoma. You are allergic to glucagon or any other inactive ingredient in GVOKE.

### **GVOKE MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:**

**High blood pressure.** GVOKE can cause high blood pressure in certain people with tumors in their adrenal glands.

**Low blood sugar.** GVOKE can cause low blood sugar in certain people with tumors in their pancreas called insulinomas by making too much insulin in their bodies.

**Serious allergic reaction.** Call your doctor or **get medical help right away** if you have a serious allergic reaction including: rash, difficulty breathing, low blood pressure

### COMMON SIDE EFFECTS

**The most common side effects of GVOKE in adults include:** nausea, vomiting, swelling at the injection site, headache

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

### BEFORE USING

Before using GVOKE, tell your doctor about all your medical conditions, including if you: have adrenal gland problems have a tumor in your pancreas, have not had food or water for a long time (prolonged fasting or starvation) have low blood sugar that does not go away (chronic hypoglycemia) are pregnant or plan to become pregnant are breastfeeding or plan to breastfeed

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### HOW TO USE

Read the detailed Instructions for Use that come with GVOKE.

Use GVOKE exactly how your healthcare provider tells you to use it

Make sure your relatives, close friends, and caregivers know where you store GVOKE and how to use it the right way **before** you need their help.

Act quickly. Having very low blood sugar for a period of time may be harmful. Your healthcare provider will tell you how and when to use GVOKE.

After giving GVOKE, your caregiver should call for emergency medical help right away.

If you do not respond after 15 minutes, your caregiver may give you another dose, if available. Tell your healthcare provider each time you use GVOKE. Low blood sugar may happen again after receiving an injection of GVOKE. Your diabetes medicine may need to be changed.

## **HOW TO STORE**

Keep GVOKE in the foil pouch until you are ready to use it. Store GVOKE at temperatures between 68°F and 77°F.

**Do not keep it in the refrigerator or let it freeze.**

Please see [Full Prescribing Information](#)

**References:** **1.** Gvoke {prescribing information}. Chicago, IL: Xeris Pharmaceuticals, Inc; 2021. **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.** Newswanger B, Prestrelski S, Andre AD. Human factor studies of a prefilled syringe with stable liquid glucagon in a simulated severe hypoglycemia rescue situation. *Expert Opin Drug Deliv.* 2019;16(9):1015-1025. **4.** National Institute of Diabetes and Digestive and Kidney Diseases. Hypoglycemia. [https://www.niddk.nih.gov/-/media/Files/Diabetes/hypoglycemia\\_508.pdf](https://www.niddk.nih.gov/-/media/Files/Diabetes/hypoglycemia_508.pdf). Published July 2021. **5.** Kedia N. Treatment of severe diabetic hypoglycemia with glucagon: an underutilized therapeutic approach. *Diabetes Metab Syndr Obes.* 2011; 4:337-346. **6.** Geller AI, Shehab N, Lovegrove MC, et al. National estimates of insulin-related hypoglycemia and errors leading to emergency department visits and hospitalizations. *JAMA Intern Med.* 2014;174(5):678-686. **7.** American Diabetes Association. Hypoglycemia (low blood sugar). <https://www.diabetes.org/healthy-living/medication-treatments/blood-glucose-testing-and-control/hypoglycemia>. Accessed September 15, 2021. **8.** American Diabetes Association. Glycemic targets: Standards of medical care in diabetes—2021. *Diabetes Care.* 2021;44(suppl 1): S73-S84.

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