PATIENT INFORMATION
GVOKE® (Gee-voke)
(glucagon)
injection, for subcutaneous use

GVOKE (Gee-voke) VIALDX™
(glucagon)
injection, for intravenous use

What is GVOKE?

GVOKE is a prescription medicine used:

- to treat very low blood sugar (severe hypoglycemia) in people with diabetes aged 2 years and older.

It is not known if GVOKE is safe and effective in children under 2 years of age.

What is GVOKE VialDx?

GVOKE VialDx is a prescription medicine used:

- to stop stomach movement (gastrointestinal motility inhibitor) in adults receiving radiology exams.

It is not known if GVOKE VialDx is safe and effective in children.

Do not use GVOKE or receive GVOKE VialDx if you:

- have a tumor in the gland on top of your kidneys (adrenal gland) called pheochromocytoma.
- have a tumor in your pancreas called insulinoma.
- have had an allergic reaction to glucagon or any of the ingredients in GVOKE or GVOKE VialDx. See the end of this Patient Information leaflet for a complete list of ingredients in GVOKE and GVOKE VialDx.

Do not receive GVOKE VialDx if you:

- have tumors in your pancreas called Glucagonomas.

Before using GVOKE or receiving GVOKE VialDx, tell your healthcare provider about all of 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).
- have diabetes mellitus.
- have heart problems.
- are pregnant or plan to become pregnant. It is not known if GVOKE or GVOKE VialDx will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if GVOKE passes into your breast milk. You and your healthcare provider should decide if you can use GVOKE while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. GVOKE and GVOKE VialDx may affect the way other medicines work, and other medicines may affect how GVOKE and GVOKE VialDx works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use GVOKE?

- Read the detailed Instructions for Use that comes 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.
- After giving GVOKE, your caregiver should **call for emergency medical help right away.**
- When you are able to safely swallow food or drink, your caregiver should give you a fast-acting source of sugar (such as a regular soft drink or fruit juice) and a long-acting source of sugar (such as crackers and cheese or a meat sandwich).
- If you do not respond to treatment 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 will I receive GVOKE VialDx?

- GVOKE VialDx will be given by a healthcare provider through a needle placed in your vein (IV infusion).

What are the possible side effects of GVOKE and GVOKE VialDx?
GVOKE and GVOKE VialDx may cause serious side effects, including:

- **high blood pressure.** GVOKE and GVOKE VialDx can cause high blood pressure in certain people with tumors in their adrenal glands.
- **low blood sugar.** GVOKE and GVOKE VialDx can cause low blood sugar in people with certain tumors in their pancreas called insulinomas by making too much insulin in their bodies. GVOKE VialDx can also cause low blood sugar in people with certain tumors called glucagonomas. Signs and symptoms of low blood sugar may include:
  - sweating
  - drowsiness
  - dizziness
  - sleep disturbances
  - irregular heartbeat
  - anxiety
  - tremor
  - blurred vision
  - hunger
  - slurred speech
  - restlessness
  - depressed mood
  - tingling in the hands, feet, lips, or tongue
  - irritability
  - abnormal behavior
  - lightheadedness
  - unsteady movement
  - inability to concentrate
  - personality changes
  - headache
- **serious allergic reaction.** Serious allergic reactions have happened in some people using products with glucagon, the active ingredient in GVOKE and GVOKE VialDx. Stop using GVOKE and call your healthcare provider or get medical help right away if you have a serious allergic reaction. If you are receiving GVOKE VialDx for a radiology exam and have a serious allergic reaction, your healthcare provider will stop the IV infusion.
  Symptoms of a serious allergic reaction include:
  - rash
  - difficulty breathing
  - low blood pressure
- **high blood sugar with GVOKE VialDx.** If you have diabetes and receive GVOKE VialDx before your radiology exam it can cause high blood sugar. Your healthcare provider will check your blood sugar levels during treatment with GVOKE VialDx.
- **heart problems with GVOKE VialDx.** If you have heart problems and receive GVOKE VialDx before your radiology exam, you may have an increase in your blood pressure and pulse while receiving GVOKE VialDx. This could be life threatening. Your healthcare provider will monitor your heart during treatment with GVOKE VialDx.

The most common side effects of GVOKE in adults include:

- nausea
- vomiting
- swelling at the injection site
- headache

The most common side effects of GVOKE in children include:

- nausea
- low blood sugar
- high blood sugar
- vomiting
- abdominal pain
- headache
- pain or redness at the injection site
- itching

The most common side effects of GVOKE VialDx include:

- nausea
- dizziness
- change in the way foods taste or loss of taste (dysgeusia)
- hot flush
- headache

These are not all the possible side effects of GVOKE and GVOKE VialDx. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GVOKE?

- Store GVOKE in the original container until time of use.
- Store at room temperature between 68°F to 77°F (20° C to 25°C).
- **Do not refrigerate or freeze.**

Keep GVOKE and all medicines out of the reach of children.

General information about the safe and effective use of GVOKE.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use GVOKE for a condition for which it was not prescribed. Do not give GVOKE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about GVOKE that is written for health professionals.

What are the ingredients in GVOKE and GVOKE VialDx?
Active ingredient: glucagon.

Inactive ingredients: trehalose dihydrate NF, sulfuric acid NF, mannitol USP (Gvoke Kit and Gvoke VialDx only), and dimethyl sulfoxide.

GVOKE is distributed by: Xeris Pharmaceuticals, Inc., Chicago, IL
For more information go to www.xerispharma.com or call 1-877-937-4737.

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