

# **INSTRUCTIONS FOR USE**

## **GVOKE KIT**

[GEE-voke k-it]

**glucagon injection**

**Subcutaneous Injection**

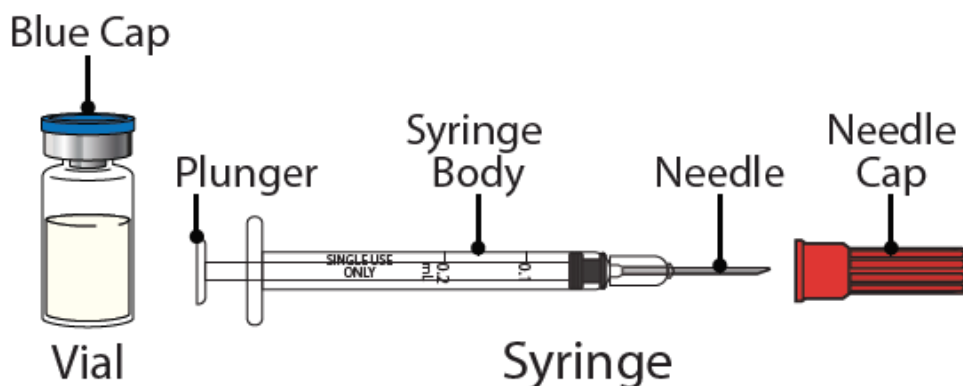
This Instructions for Use contains information on how to inject GVOKE<sup>®</sup> KIT.

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## GVOKE<sup>®</sup> KIT VISUAL

### Understanding GVOKE KIT

GVOKE KIT contains one (1) single-dose sterile syringe (29 G x ½” needle) with markings for 0.1 mL (0.5 mg pediatric dose) and 0.2 mL (1 mg adult dose), and one single-dose vial containing 0.2 mL of solution.



**Note:** Each Gvoke vial and syringe should be used only one time and then thrown away (discarded).

## STORING GVOKE KIT

### Storage Information

- Store vial and pouched syringe together in original carton until time of use. Do not remove syringe from pouch until time of use.
- Store at room temperature, 68°F to 77°F (20°C to 25°C).
- Do not refrigerate or freeze.
- Protect vial from light exposure.

## IMPORTANT INFORMATION YOU NEED TO KNOW BEFORE INJECTING GVOKE KIT

- Become familiar with the following instructions before an emergency happens.

- Do not use this product past the expiration date printed on the vial. Replace GVOKE<sup>®</sup> KIT before the expiration date on the box.
- If you have questions regarding the use of this product, talk to a healthcare provider or pharmacist.

Make sure that relatives, close friends, or caregivers know that if you become unconscious, they should call for emergency medical help right away. GVOKE KIT may have been prescribed so that relatives, close friends, and caregivers can give the injection if you become hypoglycemic (severe low blood sugar) and are unable to take sugar by mouth. If you are unconscious, GVOKE KIT can be given while awaiting medical assistance.

Show your relatives, close friends, or caregivers where you store GVOKE KIT and how to use it. They need to know how to use GVOKE KIT before an emergency happens.

### **Indications for Use**

GVOKE KIT is for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. Symptoms of severe hypoglycemia include unconsciousness and seizures or convulsions.

#### **Give GVOKE KIT if:**

1. the patient is unconscious,
2. the patient is unable to eat sugar or a sugar-sweetened product,
3. the patient is having a seizure, or
4. you have tried to give the patient sugar or drinks that are high in sugar such as a regular soft drink (soda) or fruit juice and the patient does not get better.

Milder cases of hypoglycemia should be treated promptly by eating sugar or a sugar-sweetened product. (See Information on Hypoglycemia for more information on the symptoms of low blood sugar.) GVOKE KIT will not work when taken by mouth (orally).

### **Information on Hypoglycemia**

#### **Early symptoms of hypoglycemia (low blood sugar) include:**

- |                      |  |
|----------------------|--|
| • sweating           | • hunger                                       |
| • drowsiness         | • slurred speech                               |
| • dizziness          | • depressed mood                               |
| • sleep disturbances | • tingling in the hands, feet, lips, or tongue |
| • palpitations       | • irritability                                 |
| • anxiety            | • light-headedness                             |
| • tremor             | • abnormal behavior                            |
| • blurred vision     | • inability to concentrate                     |

- unsteady movement
- headache
- personality changes

**If not treated, the patient may progress to severe hypoglycemia which can include:**

- confusion
- seizures
- unconsciousness
- death

The occurrence of early symptoms of hypoglycemia calls for quick and, if necessary, repeated administration of some form of carbohydrate. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets. The prompt treatment of mild hypoglycemic symptoms can prevent severe hypoglycemic reactions. If the patient does not improve or if administration of carbohydrate is not possible, GVOKE® KIT should be used or the patient should be treated with intravenous glucose by a medical professional.

### **Possible Problems with GVOKE KIT Treatment**

Common side effects in adults and pediatric patients are nausea and vomiting. The product may cause serious side effects including serious allergic reactions, fast heart-beat, and high blood pressure.

People may be allergic to glucagon or to one of the inactive ingredients in GVOKE KIT or may experience fast heartbeat for a short while.

If you experience any other reactions that may have been caused by GVOKE KIT, please contact your healthcare provider.

### **Important:**

- Act quickly. Prolonged unconsciousness may be harmful.
- After the injection is complete, turn the unconscious patient on his or her side to prevent them from choking in case they throw up (vomit).
- Carefully read and follow these instructions. Have a healthcare provider show you the right way to use GVOKE KIT.

### **Important Warnings**

- **Do not** remove syringe from pouch until time of use.
- **Do not** use after the expiration date has passed.
- **Do not** use if the needle cap has been removed or is damaged.
- Draw the correct dose of Gvoke: 0.1 mL for pediatric patients aged 2 to under 12 years of age weighing less than 45 kg (100 lbs) and 0.2 mL for adults and pediatric patients aged 12 years and older or pediatric patients weighing 45 kg (100 lbs) or greater.

- There will be unused medicine in the vial after use. **Do not** save unused medicine for later use. Throw away (discard) unused portion.
  - Call a healthcare provider as soon as glucagon has been injected.
- If the patient does not wake up within 15 minutes, give another dose of GVOKE<sup>®</sup> KIT and **call for emergency medical help right away**.
- **Feed the patient as soon as he or she wakes up and is able to swallow.**

**Read and become familiar with the following instructions before an emergency happens. If you have questions about using GVOKE KIT, talk with your healthcare provider or pharmacist.**

## PREPARING TO INJECT GVOKE KIT

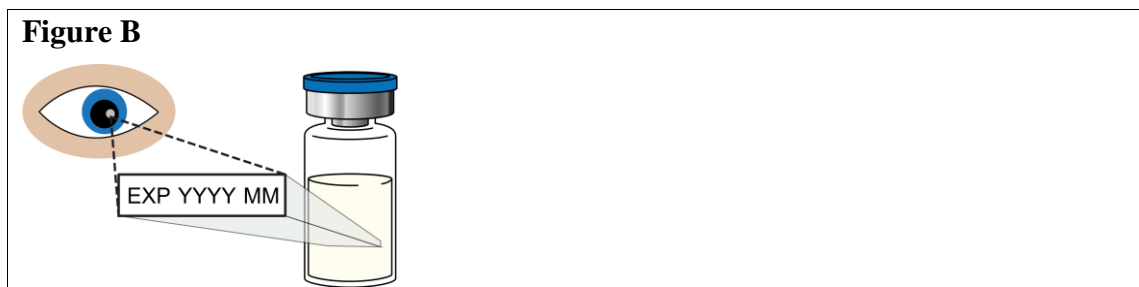
### Step 1. Remove GVOKE Vial and Syringe from Carton

- Open carton and carefully remove GVOKE vial and syringe (see [Figure A](#) ).



### Step 2. Check the Expiration Date on GVOKE Vial

- Check the expiration date printed on the label of the GVOKE vial (see [Figure B](#)).
- **Important: Do not** use the GVOKE vial if the expiration date has passed. If the GVOKE vial is expired, discard and use a new GVOKE KIT. If you do not have another GVOKE KIT to use call for emergency medical help right away.



### Step 3. Inspect the Solution in GVOKE<sup>®</sup> Vial

- Look at the liquid medicine in the vial. It must be clear and colorless, or a pale yellow (see [Figure C](#)).
- **Important: Do not** use GVOKE or inject if the liquid contains lumps, flakes, or particles.

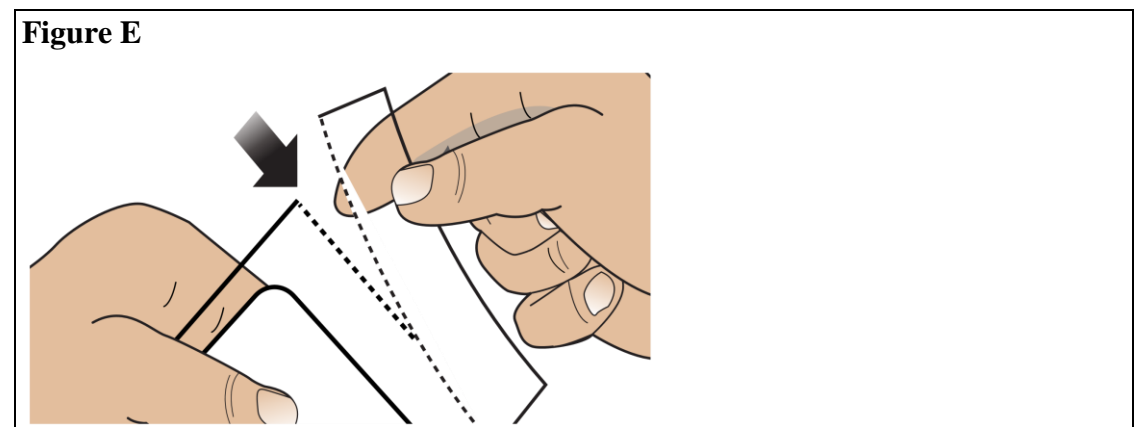


### Step 4. Prepare

- Remove the blue cap from the vial to expose the rubber stopper (see [Figure D](#)).

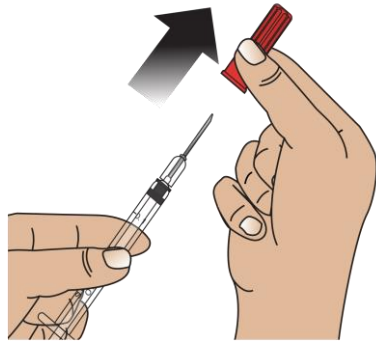


- Tear Open Pouch at Dotted Line (see [Figure E](#)). Remove syringe.



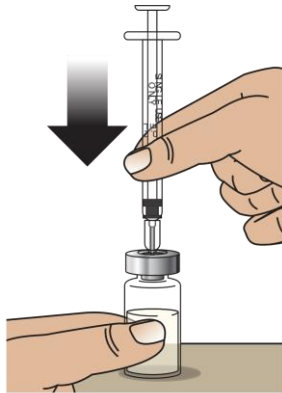
- **Pull** the needle cap straight off the syringe (see [Figure F](#)).
- **Important: Do not** put your thumb, fingers, or hand on or near the needle to help prevent accidental needle sticks.

**Figure F**



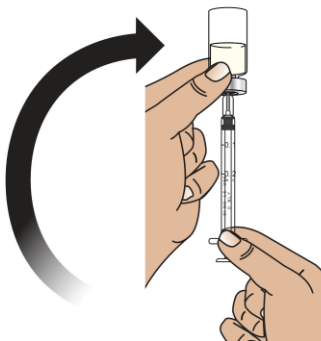
- Push the needle fully into the center of the rubber stopper (see [Figure G](#)). It is important to make sure the needle punctures within the raised circle of the stopper.

**Figure G**



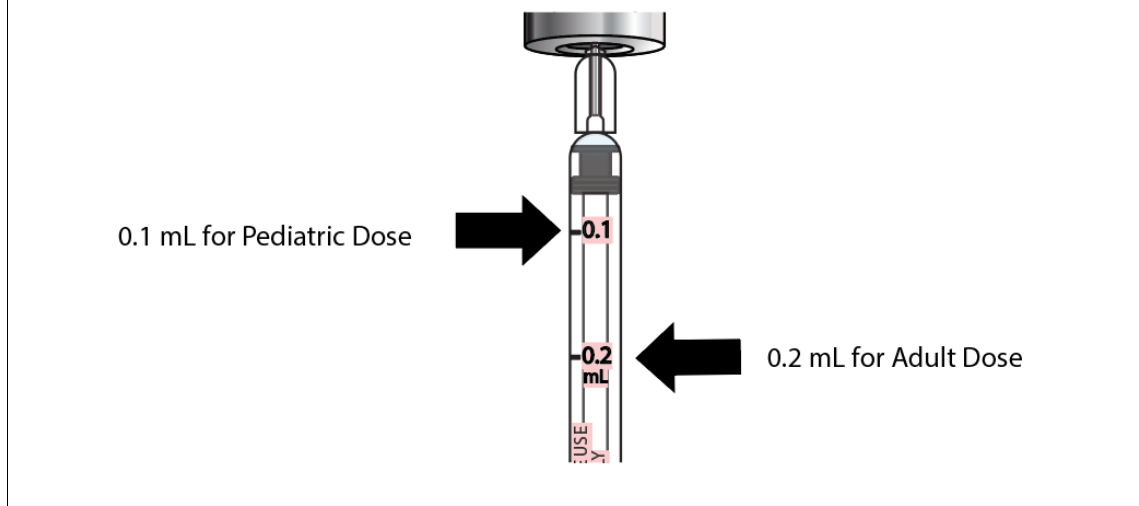
- Flip vial and syringe so vial is on top (see [Figure H](#)).

**Figure H**



- Hold the vial upside down and pull the plunger out until the mark for 0.1 mL (0.5 mg pediatric dose) or 0.2 mL (1 mg adult dose) is lined up with the plunger and remove the syringe from the vial stopper ([Figure I](#)).

**Figure I**

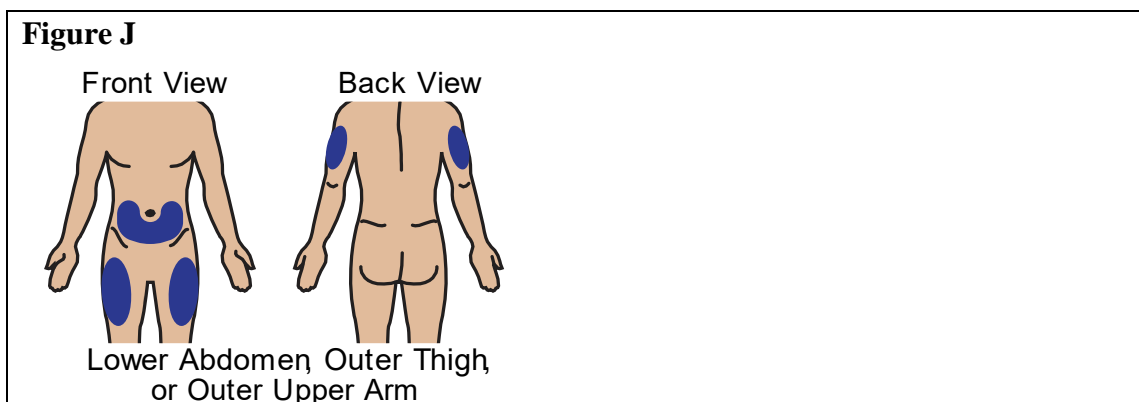


- GVOKE should be administered immediately.
- **Important:** Avoid drawing air into the syringe. If large air bubbles are drawn into the syringe, gently press the plunger to push air bubbles back into the vial and redraw the dose.
- There will be unused medicine in the vial after use. **Do not** save unused medicine for later use. Throw away (discard) unused portion.

## INJECTING GVOKE<sup>®</sup> KIT

### Step 5. Choose Injection Site and Expose Bare Skin

- Choose the lower abdomen, outer thigh, or outer upper arm for your injection site (see [Figure J](#)).

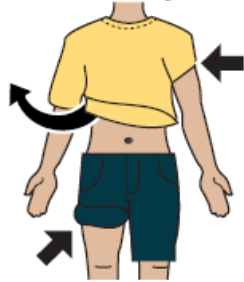


- Remove any clothing covering the injection site (see [Figure K](#)). The injection must be performed straight into the skin.
- **Important: Do not** inject through clothing.



**Figure K**

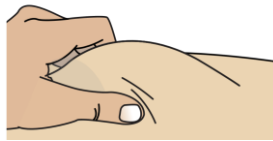
**Expose Skin of Injection Site**



**Step 6. Pinch, Insert, and Push to Start Injection**

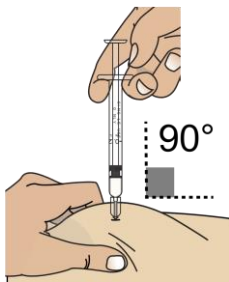
- **Pinch** the skin directly around the chosen injection site and keep pinching for the entire injection (see [Figure L](#)). This is recommended to make sure a subcutaneous (under the skin) injection is given and to prevent injection into the muscle.

**Figure L**



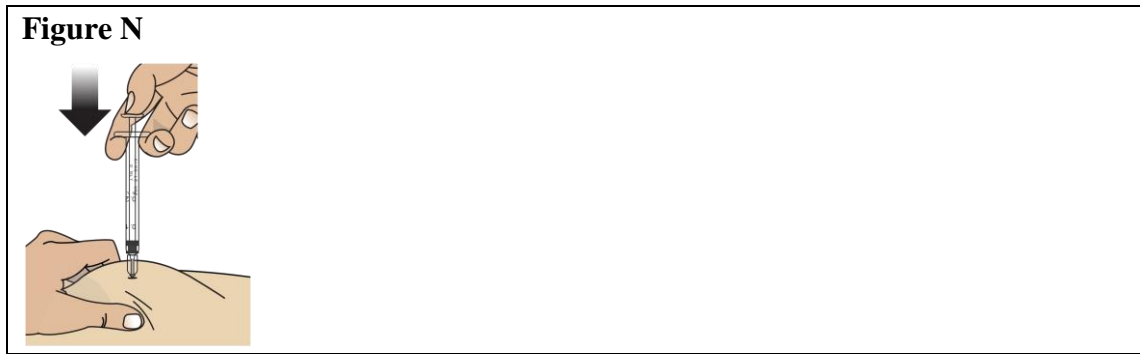
- **Without touching the plunger, insert** the needle into the skin at the injection site at a 90 degree angle (see [Figure M](#)).

**Figure M**



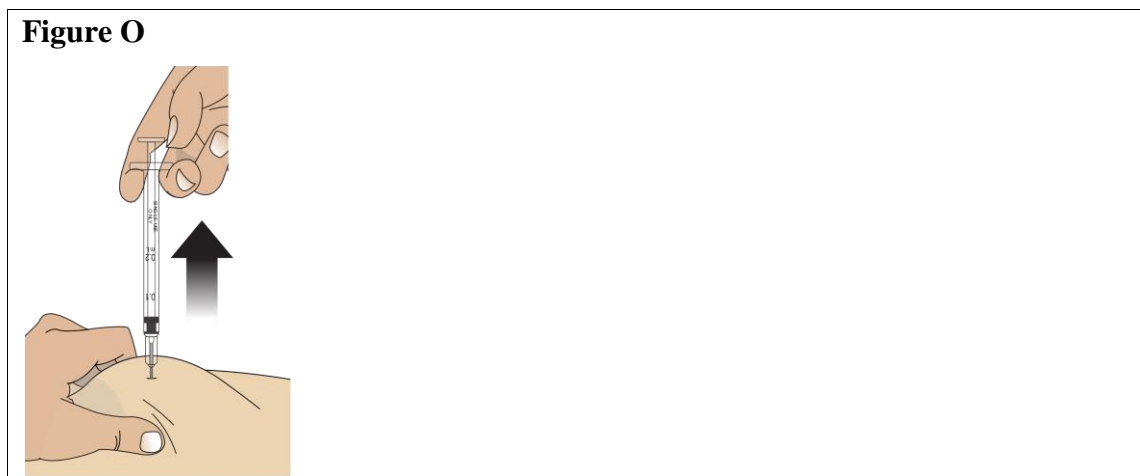
- **Push** the plunger down as far as it will go to inject all of the liquid medicine into the skin (see [Figure N](#)). You want to inject the medicine very fast to help decrease the pain.

**Important: Do not** aspirate (pull back on plunger rod) after inserting the needle. **Do not** lift up the syringe until the injection is complete.



**Step 7. Lift Away from Skin**

- Lift the syringe straight up from the injection site ([Figure O](#)).
- **Important: Do not** re-cap the syringe.



**Step 8. Turn Patient onto Side**

- When an unconscious person wakes up, he or she may throw up (vomit).
- Turn the unconscious patient on their side to prevent choking (see [Figure P](#)).



**Step 9. Make Sure Patient Receives Immediate Medical Attention After Use**

- Call for emergency medical help right after GVOKE has been injected.

- Even if GVOKE® KIT helps the patient to wake up, you should still call for emergency medical help right away.
- The patient's healthcare provider should also be notified whenever a severe drop in blood sugar (hypoglycemic reactions) happens. Hypoglycemia may happen again after receiving an injection from GVOKE KIT. The patient's diabetes medicine may need to be changed.
- Feed the patient as soon as he or she wakes up and is able to swallow. Give the patient 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 the patient does not wake up within 15 minutes, give another dose of glucagon if a second GVOKE KIT is available and notify emergency medical services right away.

## **DISPOSING OF GVOKE KIT**

### **Disposing of GVOKE KIT**

After the injection, discard vial with unused medicine and place the used syringe in a safe place until it can be disposed of in an FDA-cleared sharps container (see [Figure Q](#)). **Do not** throw away (dispose of) loose needles and syringes in your household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

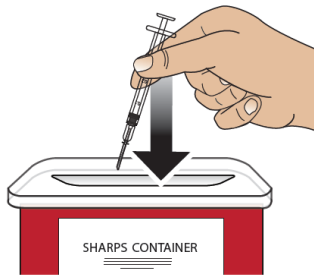
When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Always keep the sharps container out of the reach of children.

If needed, make sure to get a refill of your GVOKE KIT.

**Figure Q**



## **ADDITIONAL INFORMATION**

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

**Distributed by:**

**Xeris Pharmaceuticals, Inc.**

**Chicago, IL 60607**

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