

INSTRUCTIONS FOR USE
GVOKE HypoPen®
[GEE-voke hypo-pen]
(glucagon injection)
Auto-injector
for subcutaneous use

This “Instructions for Use” contains information on how to inject GVOKE HypoPen®

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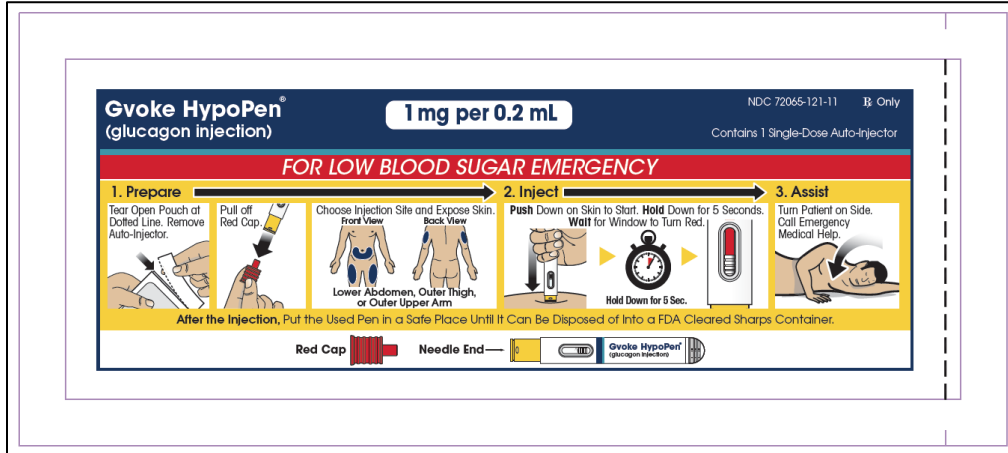
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1. GVOKE HYOPEN® VISUAL

Understanding GVOKE HypoPen

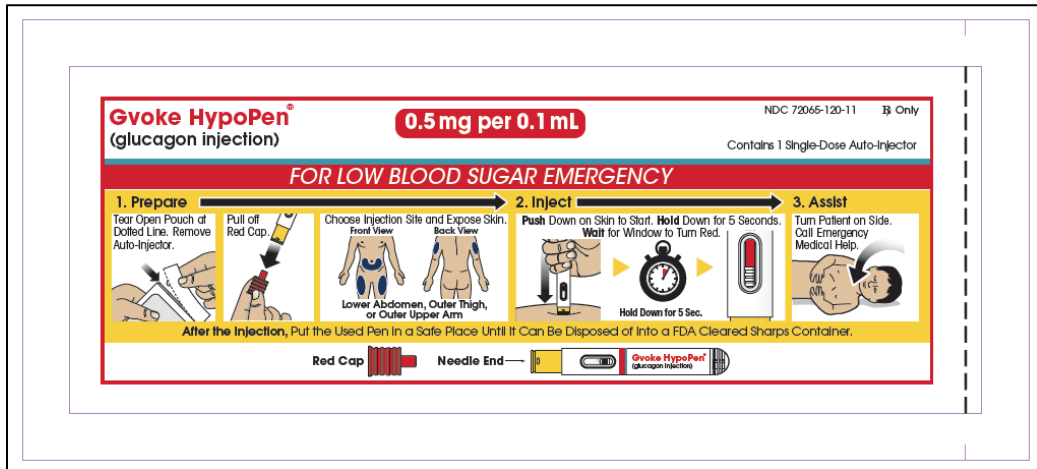
Adult GVOKE HypoPen contains a 1 mg dose of glucagon and is in a foil pouch. Below is a picture of the pouch. See the GVOKE HypoPen package for a full view of the Quick-Use Guide.

Adult GVOKE HypoPen (1 mg dose)

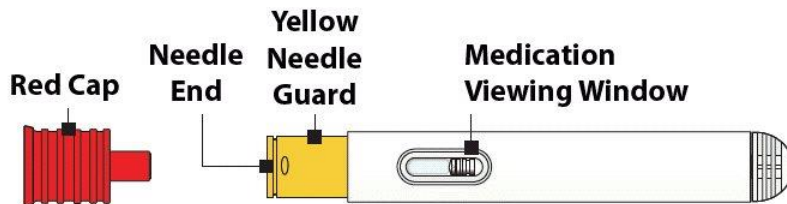


Pediatric GVOKE HypoPen contains a 0.5 mg dose of glucagon and is in a foil pouch. Below is a picture of the pouch. See the GVOKE HypoPen package for a full view of the Quick-use guide.

Pediatric GVOKE HypoPen (0.5 mg dose)



HypoPen Device



Note: GVOKE HypoPen should be used one time and then thrown away (discarded)

2. **IMPORTANT INFORMATION YOU NEED TO KNOW BEFORE INJECTING GVOKE HYPOPEN®**

- Become familiar with the following instructions before an emergency happens.
- Do not use this auto-injector past the expiration date printed on the device. Replace GVOKE HypoPen 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 HypoPen 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 HypoPen can be given while awaiting medical assistance.

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

Indications for Use

GVOKE HypoPen 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 HypoPen 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 HypoPen will not work when taken by mouth (orally).

Information on Hypoglycemia

Early symptoms of hypoglycemia (low blood sugar) include:

- sweating
- drowsiness
- dizziness
- sleep disturbances
- palpitation
- anxiety
- tremor
- blurred vision
- hunger
- slurred speech
- depressed mood
- tingling in the hands, feet, lips, or tongue
- irritability

- light-headedness
- abnormal behavior
- 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 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 impossible, GVOKE HypoPen® should be given or the patient should be treated with intravenous glucose by a medical professional.

Possible Problems with GVOKE HypoPen 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 HypoPen or may experience fast heart-beat for a short while.

If you experience any other reactions that may have been caused by GVOKE HypoPen, 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 HypoPen.

Important Warnings

- Do **not** open pouch until time of use.
- Do **not** use after the expiration date has passed.
- Do **not** use if the red needle cap has been removed or is damaged.
- Do **not** remove the red cap until you are ready to inject.
- Do **not** put or press thumb, fingers, or hand over the yellow needle guard.

- 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 HypoPen® and **call for emergency medical help right away**.
- **Feed the patient as soon as he or she wakes up and is able to swallow.**

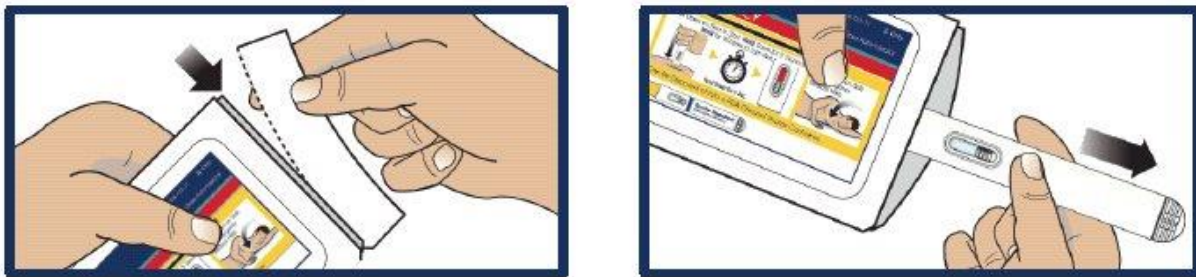
Read and become familiar with the following instructions before an emergency happens. If you have questions about using GVOKE HypoPen talk with your healthcare provider or pharmacist.

3. PREPARING TO INJECT GVOKE HYOPEN

Step 1. Remove GVOKE HypoPen from Foil Pouch

- Tear open pouch at the dotted line and carefully remove GVOKE HypoPen (see [Figure 1](#)).

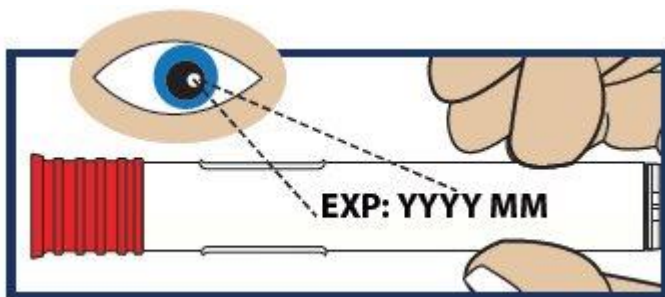
Figure 1



Step 2. Check the Expiration Date

- Check the expiration date printed on the label of GVOKE HypoPen (see [Figure 2](#)).
- **Important: Do not** use GVOKE HypoPen if the expiration date has passed. If GVOKE HypoPen is expired, throw it away in an FDA cleared sharps container and use a new GVOKE HypoPen.

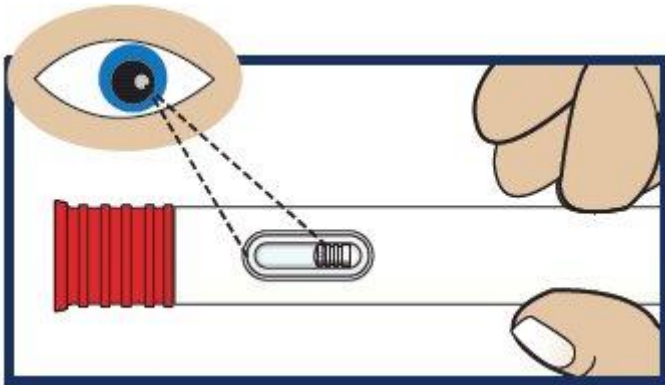
Figure 2



Step 3. Inspect the Solution

- Look at the liquid medicine through the viewing window. It must be clear and colorless, or a pale yellow (see [Figure 3](#)).
- **Important: Do not** use GVOKE HypoPen® or inject if the liquid contains lumps, flakes, or particles. **Do not** inject if solution is not visible in the viewing window.
- If you do not have another GVOKE HypoPen to use, call for emergency help right away.

Figure 3

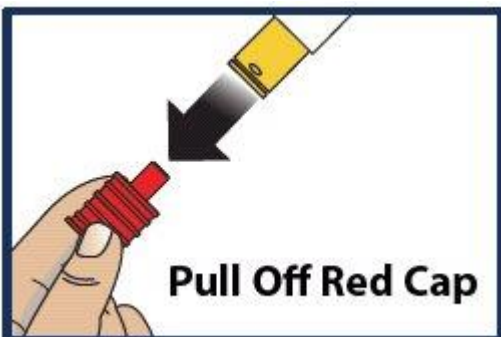


4. INJECTING GVOKE HYOPEN

Step 4. Pull Off Red Cap

- Pull the red needle cap straight off the device (see [Figure 4](#)).
- **Important: Do not** put your thumb, fingers, or hand on or near the needle guard or needle opening to help prevent accidental needle sticks.

Figure 4



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 5](#)).
- Remove any clothing covering the injection site (see [Figure 6](#)). The injection must be performed straight into the skin.
- **Important: Do not** inject through clothing.

Figure 5

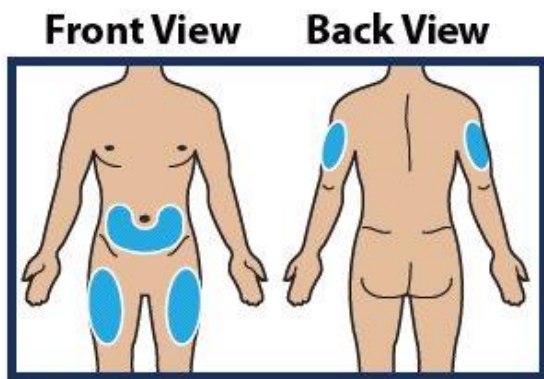


Figure 6

Expose Skin of Injection Site



Step 6. Push and Hold to Start Injection

- **Push and hold** GVOKE HypoPen® straight **down** against the injection site. Listen for a “Click”.
- **Continue to hold the device down and count slowly to 5** (see [Figure 7](#)).
- When the injection is complete, the viewing window will be red (see [Figure 8](#)).
- **Important: Do not** lift up GVOKE HypoPen until the injection is complete.

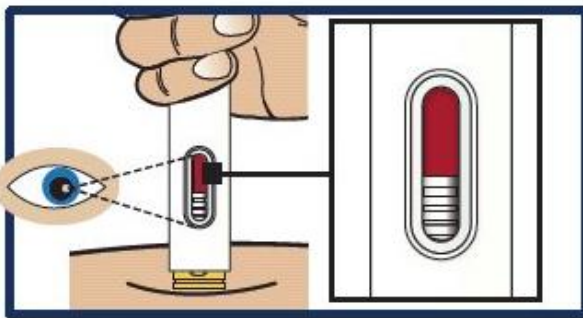
Figure 7

**Push
And Hold**

**Hold Down
For 5 Seconds**



Figure 8



Step 7. Lift Away from Skin

Lift the device straight up from the injection site (see [Figure 9](#)).

- The yellow needle guard will lock over the needle.

Figure 9

**Lift Away
From Skin**

**Yellow Needle Guard
Locks Over Needle**

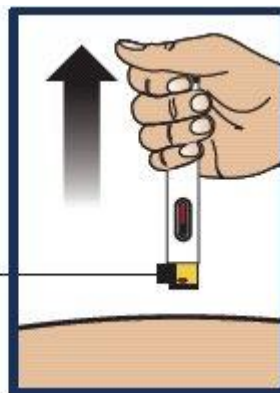
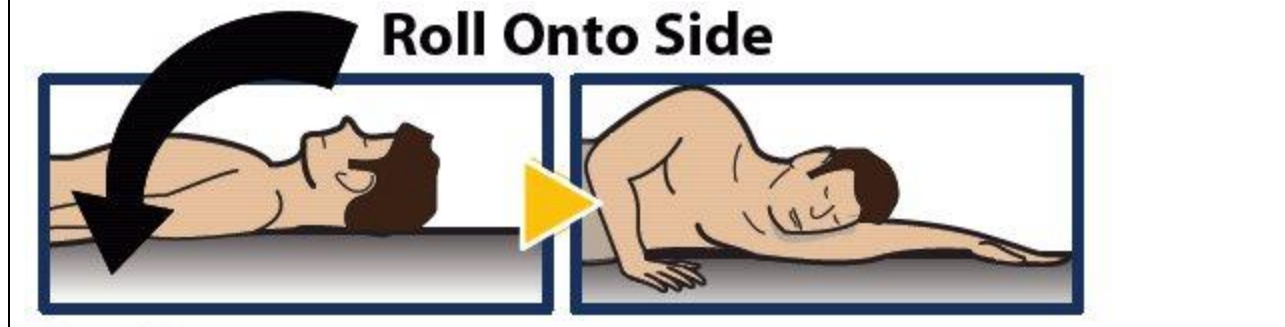


Figure 9

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 10](#)).

Figure 10



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

- Call for emergency medical help right after GVOKE HypoPen® has been injected.
- Even if GVOKE HypoPen 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 HypoPen. 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 longacting 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 HypoPen is available and notify emergency medical services right away.

5. STORING GVOKE HYPOPEN

Storage Information

- Store in sealed original foil pouch until time of use.
- Store at room temperature, 68° to 77°F (20° to 25°C).
- Do not refrigerate or freeze.

6. DISPOSING OF GVOKE HYPOPEN®

Re-cap and Dispose of GVOKE HypoPen in an FDA Cleared Sharps Disposal Container

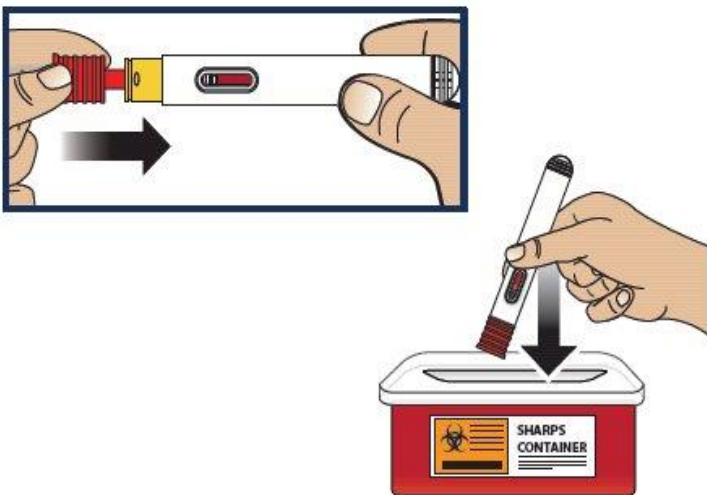
If a puncture-resistant sharps container is not available, carefully re-cap and store GVOKE HypoPen in a safe place until it can be disposed of into a FDA cleared sharps container (see [Figure 11](#)).

- Do not throw away (dispose of) loose needles and syringes in your household trash. If you do not have a 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. Always keep the sharps container out of the reach of children. If needed, make sure to get a refill of GVOKE HypoPen.

Figure 11



7. ADDITIONAL INFORMATION

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

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