

INSTRUCTIONS FOR USE

GVOKE® PFS

[GEE-voke P-F-S]

(glucagon injection)

pre-filled syringe

for subcutaneous use

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

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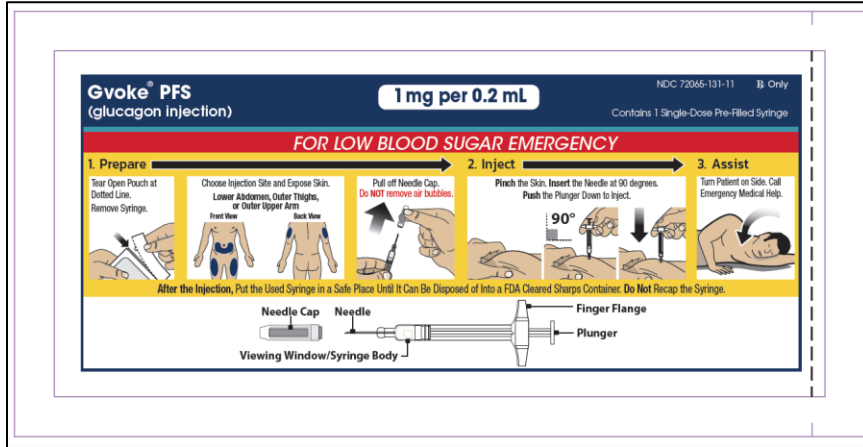
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1. GVOKE® PFS VISUAL

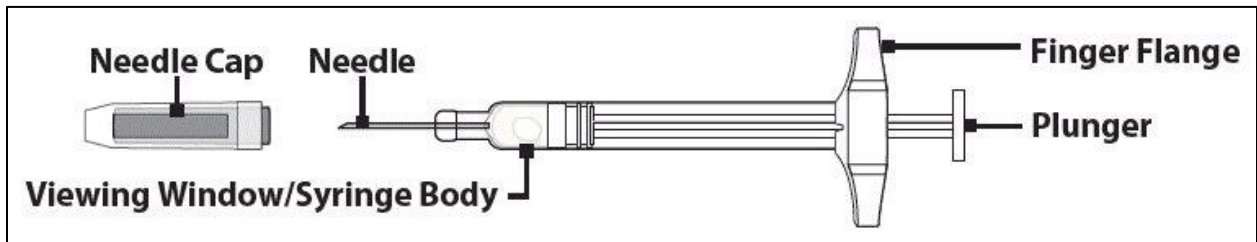
Understanding GVOKE PFS

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

GVOKE PFS (1 mg dose)



PFS Device



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

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

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

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

Indications for Use

GVOKE PFS 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 PFS 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 PFS 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® PFS should be given or the patient should be treated with intravenous glucose by a medical professional.

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

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

Important Warnings

- **Do not** open 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.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange from the syringe.

- Call a healthcare provider as soon as GVOKE® PFS has been injected.
- If the patient does not wake up within 15 minutes, give another dose of GVOKE PFS and **call for emergency medical help right away.**
- **Feed the patient as soon as he or she wakes up and is able to swallow.**

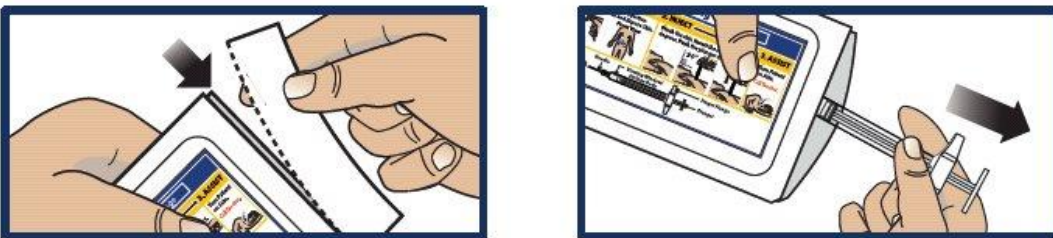
Read and become familiar with the following instructions before an emergency happens. If you have questions about using GVOKE PFS, talk with your healthcare provider or pharmacist.

3. PREPARING TO INJECT GVOKE® PFS

Step 1. Remove GVOKE PFS from Foil Pouch

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

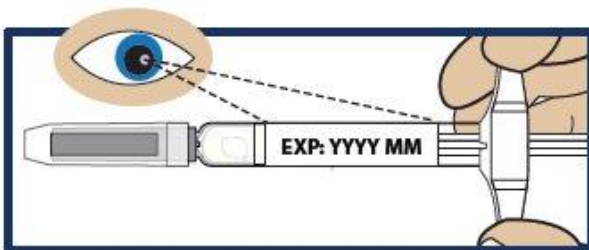
Figure 1



Step 2. Check the Expiration Date

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

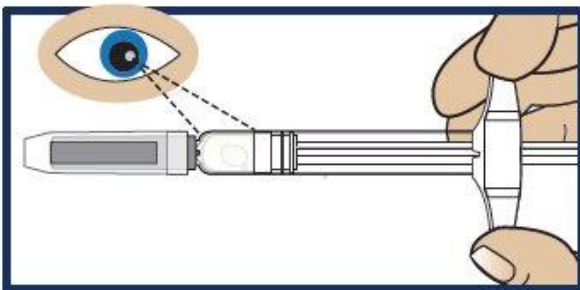
Figure 2



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](#)).
- It is normal to see air bubbles in the medicine.
- **Important: Do not** try to remove air bubbles before injecting.
- **Do not** use GVOKE® PFS 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 PFS to use, call for emergency help right away.

Figure 3



4. INJECTING GVOKE® PFS

Step 4. Choose Injection Site and Expose Bare Skin

- Choose the lower abdomen, outer thigh, or outer upper arm for your injection site (see [Figure 4](#)).
- Remove any clothing covering the injection site (see [Figure 5](#)). The injection must be performed straight into the skin.
- **Important: Do not** inject through clothing.

Figure 4

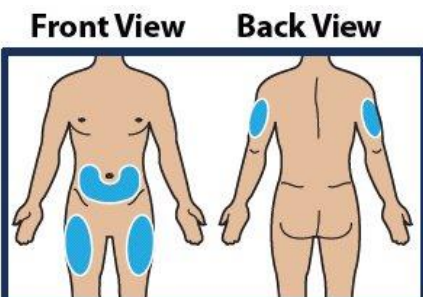
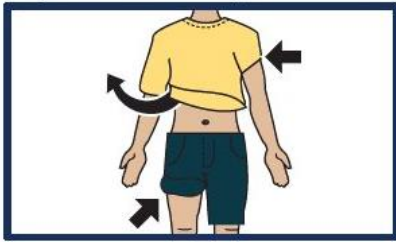


Figure 5

Expose Skin of Injection Site

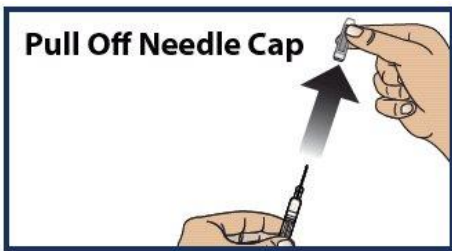


Step 5. Pull off the Needle Cap

- **Pull** the needle cap straight off the syringe (see [Figure 6](#)).
- **Important: Do not** put your thumb, fingers, or hand on or near the needle to help prevent accidental needle sticks.

Figure 6

Pull Off Needle Cap



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 7](#)). This is recommended to make sure a subcutaneous (under the skin) injection is given and to prevent injection into the muscle.
- **Without touching the plunger, insert** the needle into the skin at the injection site at a 90-degree angle (see [Figure 8](#)).
- **Push** the plunger down as far as it will go to inject all of the liquid medicine into the skin (see [Figure 9](#)). 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. **Push** the plunger down as far as it will go. **Do not** lift up GVOKE® PFS until the injection is complete.

Figure 7

Pinch



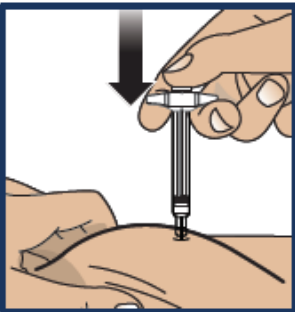
Figure 8

Insert



Figure 9

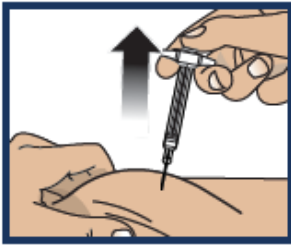
Push



Step 7. Lift Away from Skin

- Lift the syringe straight up from the injection site (see [Figure 10](#)).
- **Important: Do not** re-cap the syringe.

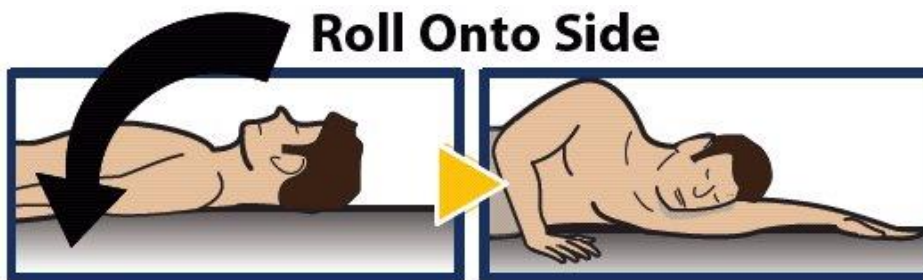
Figure 10



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 11](#)).

Figure 11



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

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

5. STORING GVOKE® PFS

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® PFS

Dispose of GVOKE PFS in an FDA Cleared Sharps Disposal Container

To prevent injury caused from contact with the used needle, put the used syringe in a safe place until it can be disposed of into a FDA cleared sharps container right away after use (see [Figure 12](#)). **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 PFS.

Figure 12



7. ADDITIONAL INFORMATION

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

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