

Louis is an adult with PNH who's taken EMPAVELI.

Your guide to self-administration with the **EMPAVELI Injector**

PNH=paroxysmal nocturnal hemoglobinuria.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is EMPAVELI[®] (pegcetacoplan)?

EMPAVELI is a prescription medicine used to treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH).

What is the most important information I should know about EMPAVELI?

EMPAVELI is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

EMPAVELI increases your chance of getting serious infections caused by encapsulated bacteria such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.

1. You must complete or be up to date with the vaccines against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of EMPAVELI.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information, Medication Guide, and Instructions for Use.

EMPAVELI self-administration may fit into your lifestyle

EMPAVELI is a PNH treatment that you give yourself at home or wherever works for you, after receiving proper training. Each EMPAVELI injection should take approximately 30 to 60 minutes.

EMPAVELI is administered subcutaneously (just under the skin) with the EMPAVELI Injector. With EMPAVELI self-administration, there's no need to plan days or vacations around infusion center visits.

- ✓ No intravenous (IV) infusions
- ✓ No infusion center visits
- ✓ No need to plan around infusion appointments



- ▶ Push button starts injection and pops up when injection is complete
- ▶ The needle is never seen
- ▶ Compact device with no tubing involved
- ▶ The gauge shows the injection progress

PNH=paroxysmal nocturnal hemoglobinuria.

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Self-administration with the **EMPAVELI Injector**

This guide will provide the steps to self-administering EMPAVELI. Please read them carefully to ensure you know how to use EMPAVELI correctly.

A doctor or qualified healthcare professional should show you or your caregiver how to administer EMPAVELI the right way before you use it for the first time.

Whenever you administer EMPAVELI, remember to record the lot numbers and expiration dates from the EMPAVELI Injector and vial in your CareKit Treatment Journal.

"No more scheduling around IV infusions. Now, I have more control."

Monica is an adult who's taken EMPAVELI.
Individual experiences may vary.

—Monica

Before you begin, please read the Instructions for Use that came with your medication

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

EMPAVELI administration should be done at regular intervals twice a week or as instructed by your healthcare provider.*

Self-administration with the EMPAVELI Injector should take approximately 30 to 60 minutes.

*If there is an increase in your lactate dehydrogenase (LDH), an enzyme in your blood, your healthcare provider may tell you to take EMPAVELI every 3 days.

1080-mg dose
2x
WEEKLY*
For ~30-60 minutes

Your **Apellis Care Educator (ACE)** is there for you from the start. They will provide you:

- ▶ 1-on-1 training on how to self-administer EMPAVELI in your home or virtually
- ▶ Ongoing support every step of the way
- ▶ A wide variety of educational resources
- ▶ Answers to questions that may pop up

ApellisAssist

1-866-MY-APL-ASSIST (1-866-692-7527)
from 8 AM-8 PM ET, Monday-Friday

They can also connect you to a PANTHERx®
Rare pharmacist who is on call 24 hours a day.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full [Prescribing Information](#) and [Medication Guide](#).

Preparing EMPAVELI for injection



Start here

Read the instructions on EMPAVELI preparation for use on pages 6-10. The EMPAVELI Injector administration instructions begin on page 11.

Important information for EMPAVELI

- ▶ Store vials of EMPAVELI in the refrigerator between 36°F to 46°F (2°C-8°C) in the original carton to protect from light
- ▶ **Do not** use EMPAVELI past the expiration date stamped on the carton

Keep EMPAVELI, the EMPAVELI Injector, and all medicines out of the reach of children.

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

Step 1

Prepare for injection

Before you start:

- ✓ Find a well-lit, flat work surface area, like a table
- ✓ Remove a single vial carton from the refrigerator. Keep the vial in the carton at room temperature and allow it to warm up for about **30 minutes**
- ⚠ **Do not** try to speed up the warming process
- ✓ Gather your supplies
- ✓ Clean your flat work surface well using an alcohol wipe
- ✓ Wash your hands thoroughly with soap and water. Dry your hands

Supplies needed for injection, must be obtained separately



For illustration only. The supplies you receive may look different.

Make sure your space is away from pets or small children

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information and Medication Guide.

Step 2

Check the vial and liquid



- ▶ Remove the vial from the carton. Carefully look at the liquid in the vial of EMPAVELI
- ▶ EMPAVELI is a clear, colorless to slightly yellowish liquid. Check for particles or color changes

⚠ Do not use and call ApellisAssist® if:

- ▶ The liquid looks cloudy, contains particles, or is dark yellow
- ▶ The protective flip cap is missing or damaged
- ▶ The expiration date on the label has passed



- ▶ Flip up to remove the protective flip cap from the top of the vial to show the exposed middle part of the gray rubber stopper of the EMPAVELI vial
- ▶ Throw away the cap



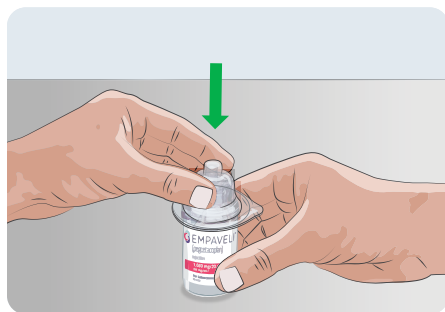
- ▶ Clean the stopper on top of the vial with a new alcohol wipe
- ▶ Allow the stopper to dry for at least 30 seconds
- ⚠ **Do not** touch the exposed gray rubber stopper after wiping

Step 3

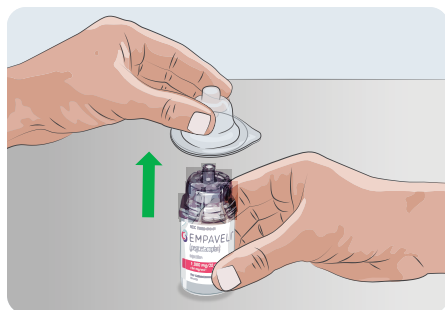
Prepare and fill the syringe with EMPAVELI using a needleless transfer device (such as a vial adapter)

Always follow the Instructions for Use provided by the needleless transfer device's manufacturer (as they may differ from the following steps).

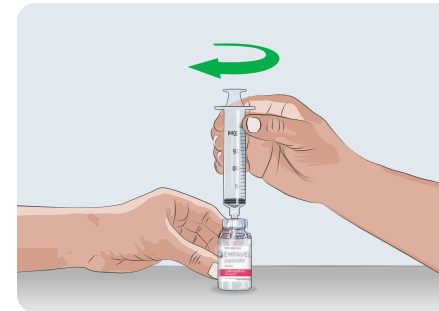
- ⚠ **Do not** remove the needleless transfer device from the blister package
- ⚠ **Do not** touch the spike or the inside of the needleless transfer device
- ⚠ **Do not** use the needleless transfer device if it comes out or is dropped out of the package
- ⚠ **Do not** use the needleless transfer device if the package is opened



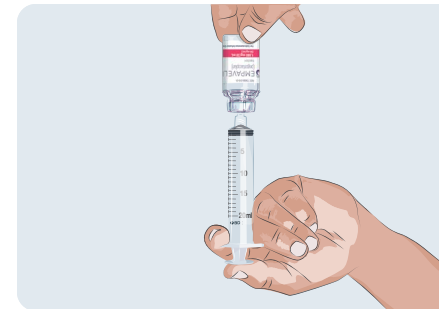
- ▶ Remove the cover of the needleless transfer device package
- ▶ Place the vial on a clean, flat surface and hold the vial by the base with one hand
- ▶ Using the outside of the blister package to firmly hold the needleless transfer device, push the needleless transfer device straight down onto the vial top until it snaps securely into place



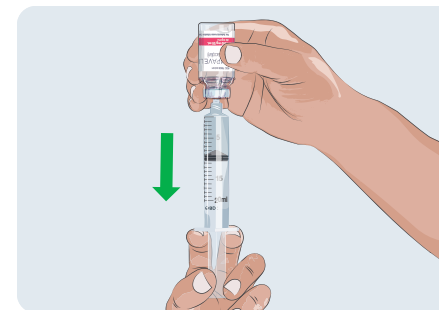
- ▶ Remove the blister package from the needleless transfer device and throw the blister package away
- ⚠ **Do not** touch the connector at the top of the transfer device



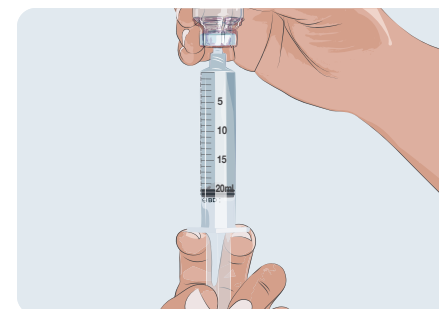
- ▶ Remove the syringe from its packaging
- ⚠ **Do not** touch the tip of the syringe
- ▶ Attach the syringe to the needleless transfer device by twisting the tip of the syringe to the right (clockwise) onto the top of the needleless transfer device



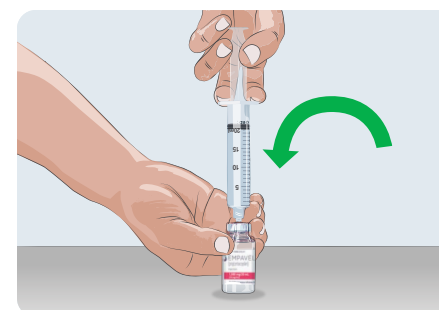
- ▶ Turn the vial upside down



- ▶ Slowly pull the syringe plunger down to fill the syringe with EMPAVELI



- ▶ Withdraw all the EMPAVELI from the vial into the syringe
- ▶ Make sure there is 20 mL of EMPAVELI in the syringe
- ▶ Remove air from syringe by pushing the plunger gently

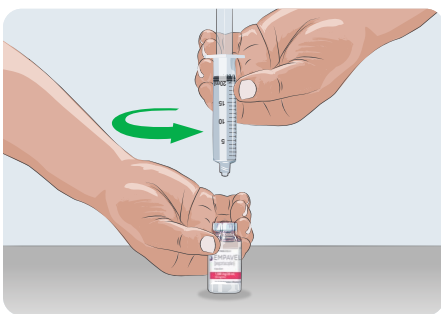


- ▶ While holding the EMPAVELI vial and syringe, turn the EMPAVELI vial and filled syringe upright and place the bottom of the vial on a flat surface

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information and Medication Guide.

Step 3

Prepare and fill the syringe with EMPAVELI using a needleless transfer device (such as a vial adapter) (cont'd)



- ▶ Remove the filled syringe from the needleless transfer device with one hand, while holding the EMPAVELI vial with the other hand and twisting the filled syringe to the left (counterclockwise)



- ▶ Set the syringe down on a clean, flat surface while you prepare the EMPAVELI Injector. The syringe will not leak when set down

⚠ **Do not** touch the tip of the filled syringe



- ⚠ **Do not** remove the needleless transfer device from the vial
- ▶ Throw away the vial with the needleless transfer device attached into the household trash

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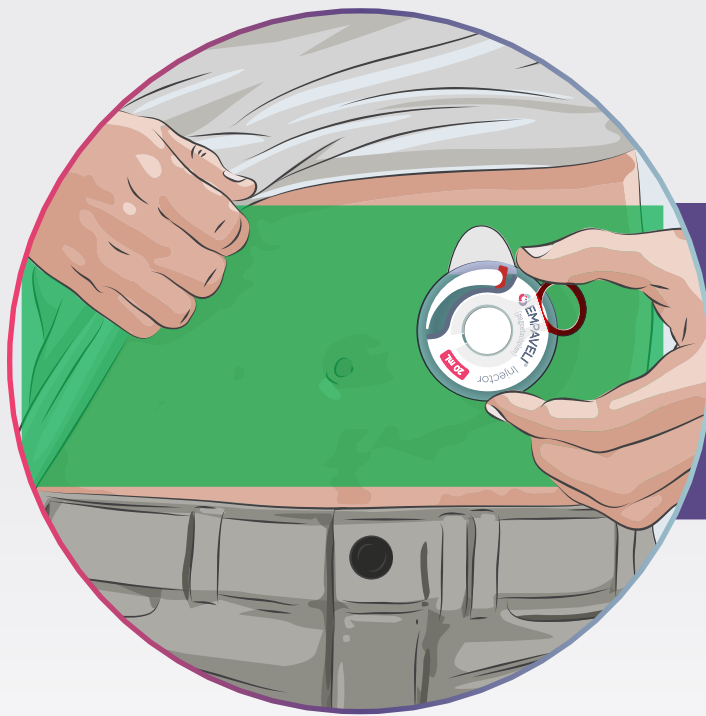
Using the EMPAVELI Injector

When you've completed all of the steps in the previous section called Preparing EMPAVELI for Injection, you're ready to begin using the EMPAVELI Injector.

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

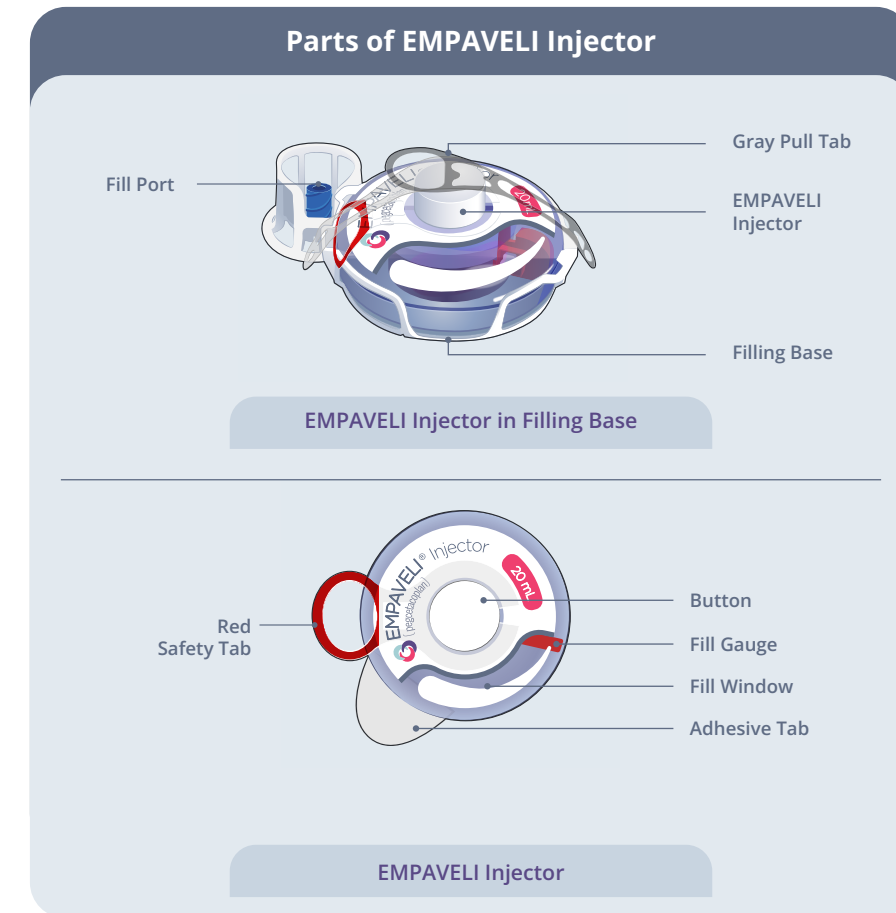
Using the EMPAVELI Injector

Do not proceed to these instructions before completing the syringe filling instructions on pages 5 to 10.



Once you complete the following steps, the end result is to attach the EMPAVELI Injector on your stomach.

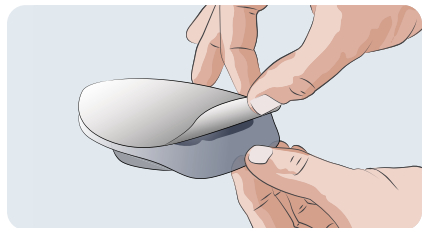
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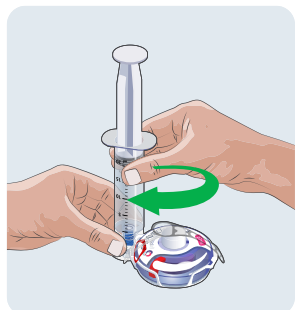
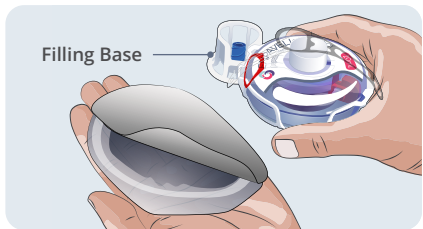
- ### Supplies required for injection
- Alcohol Wipe
 - Syringe Filled With EMPAVELI
 - EMPAVELI Injector Packaging
 - Sharps Container

Step 4

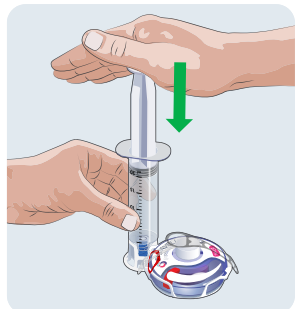
Fill the injector with EMPAVELI liquid



- ▶ Peel back the cover and remove the clear packaging insert
- ▶ Remove the EMPAVELI Injector and the surrounding Filling Base from the packaging. Place it on a clean, flat surface



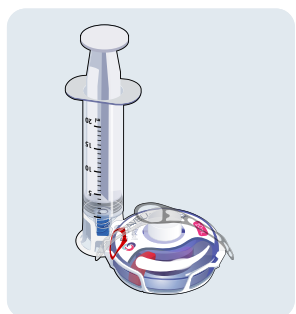
- ▶ Pick up the syringe filled with EMPAVELI
- ▶ Twist the filled syringe tip to the right (clockwise) into the Fill Port until it is tight



- ▶ Firmly push the syringe plunger down
- ▶ The syringe plunger may be hard to push
- ▶ Watch the Fill Gauge move as EMPAVELI is pushed into the injector



Fill Gauge



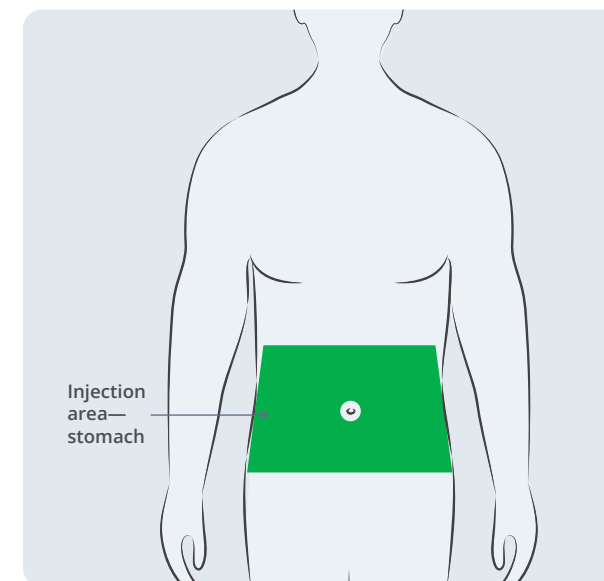
- ▶ Make sure the syringe is empty. If needed, press firmly down on the syringe plunger again
- ⚠ **Do not** remove syringe from Filling Base. After the EMPAVELI Injector is filled, continue with the preparation and injection
- ⚠ **Do not** store the filled EMPAVELI Injector

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information and Medication Guide.

Step 5

Attach the EMPAVELI Injector to stomach

- ▶ Determine where to place the EMPAVELI Injector on your stomach
- ⚠ Use the EMPAVELI Injector on stomach only
- ▶ Choose an injection site at least:
 - 1 inch from the edge of your belly button and the edge of the EMPAVELI Injector, and
 - 1 inch from the last injection site
- ⚠ Avoid an injection site that is tender, bruised, red, hard, irritated, scarred, tattooed, or has stretch marks
- ⚠ **Do not** apply the EMPAVELI Injector along the belt line or on areas where the injector will be affected by folds in the skin
- ⚠ Wear loose clothes so that they **do not** get in the way of the EMPAVELI Injector

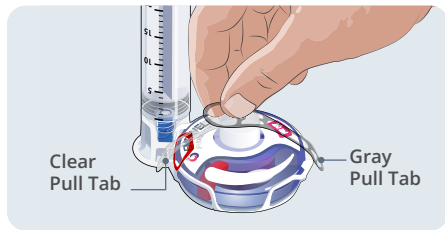


Step 5

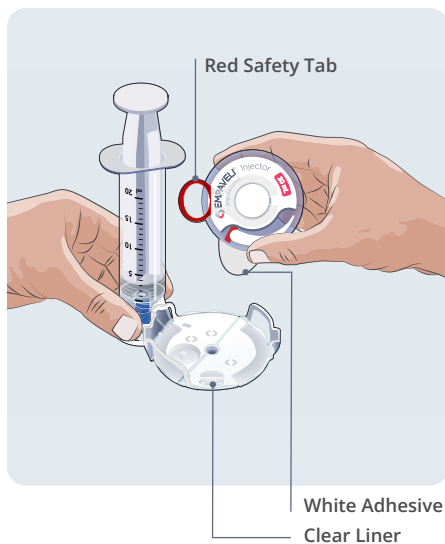
Attach the EMPAVELI Injector to stomach (cont'd)



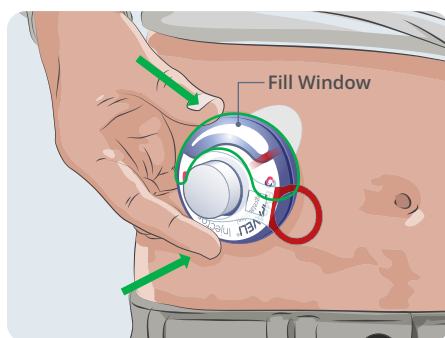
- ▶ Clean the injection site with an alcohol wipe
- ▶ Allow the injection site to dry for at least 30 seconds
- ⚠ **Do not** let your clothes touch the clean injection site



- ▶ Hold the Gray Pull Tab and pull. Allow both the Gray and Clear Pull Tabs to fall to the side
- ▶ Both tabs may fall to the side or come off completely
- ⚠ **Do not** remove the Red Safety Tab until the EMPAVELI Injector is attached to your body



- ▶ Hold the sides of the EMPAVELI Injector and pull it straight up to remove it from the Filling Base
- ⚠ **Do not** touch the adhesive on the bottom of the EMPAVELI Injector or fold the adhesive onto itself
- ▶ The White Adhesive will stay attached to the EMPAVELI Injector and the Clear Liner will stay attached to the Filling Base
- ⚠ **Do not** remove the Red Safety Tab until the EMPAVELI Injector is attached to your body
- ⚠ Ensure injection site has been cleaned before attaching the EMPAVELI Injector

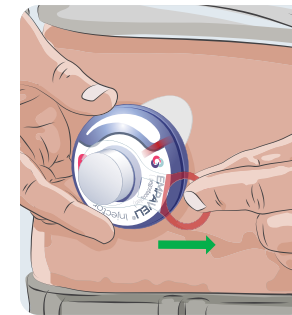


- ▶ Position the EMPAVELI Injector so the Fill Window is pointed up toward your face
- ▶ Press firmly on the clear portion of the EMPAVELI Injector to attach to your stomach
- ⚠ **Do not** use anything to hold the EMPAVELI Injector in place

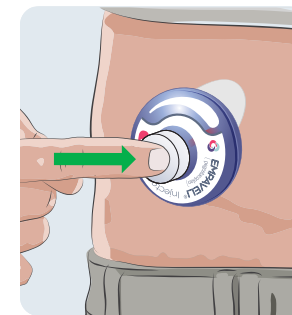
Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information and Medication Guide.

Step 6

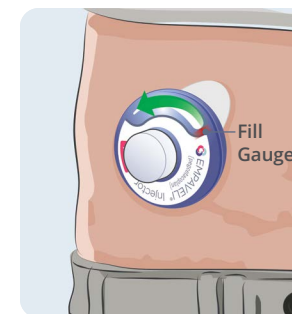
Start injection



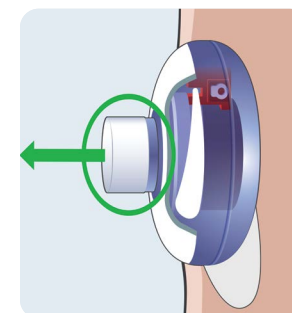
- ▶ Hold the EMPAVELI Injector with one hand. Use your other hand to pull the Red Safety Tab off
- ▶ The injection will not start until the Red Safety Tab is removed



- ▶ Right away, press the button in firmly until it stays in place to start the EMPAVELI injection
- ⚠ Pushing the button will insert the needle into your skin. You may feel the needle go into your skin
- ▶ Light daily activities can be done during injection
- ⚠ Be careful not to bump or knock the EMPAVELI Injector or button during injection
- ⚠ During the injection keep your stomach totally dry. Avoid intense physical activity. **Do not** sleep or bathe during the injection



- ▶ Your EMPAVELI injection will continue as long as the button is pushed in. It may take approximately 30 to 60 minutes to complete
- ▶ To track progress, watch the Fill Gauge move across Fill Window toward empty. It may take some time to move and may move slowly
- ⚠ **Do not** remove the EMPAVELI Injector until the button pops out
- ⚠ If the button does not pop out after 2 hours, refer to Questions and Answers in the EMPAVELI Injector Instructions for Use
- ⚠ If the EMPAVELI Injector falls off of your body, refer to the Questions and Answers in the Instructions for Use
- ⚠ **Caution:** Holding down the button will stop the flow of medicine. The injection will begin again when the button is released
- ⚠ If you have an allergic reaction to the adhesive, call your healthcare provider right away



- ▶ When the button pops out, the injection is done, and the needle is pulled out of the skin, back into the EMPAVELI Injector
- ⚠ The button popping out is the only way to know if the injection is complete. **Do not** remove the EMPAVELI Injector until the button pops out

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

Step 7

Remove and dispose of the EMPAVELI Injector



- ▶ Use your thumb to lift the Adhesive Tab. Hold the Adhesive Tab against the EMPAVELI Injector
- ▶ Slowly peel the EMPAVELI Injector away from your skin



- ▶ Put your used EMPAVELI Injector in an FDA-cleared sharps disposal container right away after use
- ⚠ **Do not** throw away the EMPAVELI Injector in the household trash
- ▶ The Filling Base with syringe attached, alcohol wipe, and packaging may be placed 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, and
 - 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

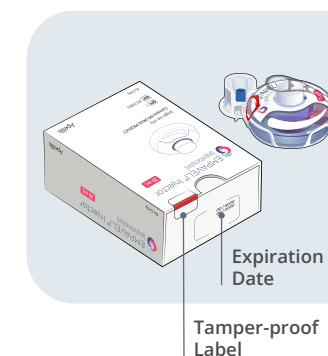
- ▶ **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this
- ▶ **Do not** recycle your used sharps disposal container
- ▶ There may be state or local laws about how you should throw away used needles and syringes. For more information 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 [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal)
- ▶ Keep the used EMPAVELI Injector and sharps disposal container away from children

How to store the EMPAVELI Injector

- ▶ Keep the EMPAVELI Injector unit in the unopened tray inside the original box
- ▶ **Do not** open the tray until ready for injection
- ▶ **Store** the EMPAVELI Injector unit in a clean, dry area away from heat and sunlight, at room temperature from 36°F to 86°F (2°C-30°C)
- ▶ Use the EMPAVELI Injector where the temperature is 41°F to 104°F (5°C-40°C)

General information

- ▶ EMPAVELI Injector is for abdominal subcutaneous use only
- ▶ EMPAVELI Injector has a fill capacity of 20 mL



Please refer to the EMPAVELI Injector Instructions for Use for additional important information, including Questions and Answers.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information and Medication Guide.

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

INDICATION AND IMPORTANT SAFETY INFORMATION

What is EMPAVELI® (pegcetacoplan)?

EMPAVELI is a prescription medicine used to treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH).

What is the most important information I should know about EMPAVELI?

EMPAVELI is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

EMPAVELI increases your chance of getting serious infections caused by encapsulated bacteria such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.

- 1. You must complete or be up to date with the vaccines against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of EMPAVELI.**
- If you have not completed your vaccines and EMPAVELI must be started right away, you should receive the required vaccines as soon as possible.
- If you have not been vaccinated and EMPAVELI must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
- If you have been vaccinated against these bacteria in the past, you might need additional vaccines before starting EMPAVELI. Your healthcare provider will decide if you need additional vaccines.
- Vaccines do not prevent all infections caused by encapsulated bacteria. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
 - ▶ fever with or without shivers or the chills
 - ▶ fever with chest pain and cough
 - ▶ fever with high heart rate
 - ▶ headache and a fever
 - ▶ confusion
 - ▶ clammy skin
 - ▶ fever and a rash
 - ▶ fever with breathlessness or fast breathing
 - ▶ headache with nausea or vomiting
 - ▶ headache with a stiff neck or stiff back
 - ▶ body aches with flu-like symptoms
 - ▶ eyes sensitive to light

Please see additional Important Safety Information on page 22, and see full Prescribing Information, including Boxed WARNING regarding risk of serious infections, and Medication Guide for additional information.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about EMPAVELI? (cont'd)

Your healthcare provider will give you a Patient Safety Card about the risk of serious infections. Carry it with you at all times during treatment and for 2 months after your last EMPAVELI dose. Your risk of serious infections may continue for several weeks after your last dose of EMPAVELI. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

EMPAVELI is only available through a program called the EMPAVELI Risk Evaluation and Mitigation Strategy (REMS). Before you can take EMPAVELI, your healthcare provider must enroll in the EMPAVELI REMS program, counsel you about the risk of serious infections caused by certain bacteria, give you information about the symptoms of serious infections, make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that you receive antibiotics if you need to start EMPAVELI right away and you are not up to date on your vaccines, and give you a Patient Safety Card about your risk of serious infections.

Who should NOT take EMPAVELI?

Do not take EMPAVELI if you:

- ▶ are allergic to pegcetacoplan or any of the ingredients in EMPAVELI.
- ▶ have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B when you are starting EMPAVELI treatment.

Before you take EMPAVELI, tell your healthcare provider about all of your medical conditions, including if you:

- ▶ have an infection or fever.
- ▶ are pregnant or plan to become pregnant. EMPAVELI may harm your unborn baby. Females who are able to become pregnant should have a pregnancy test before starting treatment with EMPAVELI and use an effective method of birth control during treatment with EMPAVELI and for 40 days after the last dose.
- ▶ are breastfeeding or plan to breastfeed. It is not known if EMPAVELI passes into your breast milk. You should not breastfeed during treatment with EMPAVELI and for 40 days after the last dose.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

If you stop taking EMPAVELI, your healthcare provider will need to monitor you closely for at least 8 weeks after stopping EMPAVELI. Stopping treatment with EMPAVELI may cause a breakdown of red blood cells due to PNH.

Symptoms or problems that can happen due to red blood cell breakdown include:

- ▶ decreased hemoglobin level in your blood
- ▶ blood in your urine
- ▶ shortness of breath
- ▶ trouble swallowing
- ▶ tiredness
- ▶ pain in the stomach (abdomen)
- ▶ blood clots
- ▶ erectile dysfunction (ED)

What are the possible side effects of EMPAVELI?

EMPAVELI can cause serious side effects including allergic reactions. Allergic reactions can happen during your EMPAVELI infusion. Stop your EMPAVELI infusion and tell your healthcare provider or get emergency medical care right away if you get any of these symptoms during your EMPAVELI infusion:

- ▶ chest pain
- ▶ trouble breathing or shortness of breath
- ▶ swelling of your face, tongue, or throat
- ▶ feel faint or pass out

The most common side effects in people with PNH treated with EMPAVELI include injection-site reactions; infections; diarrhea; pain in the stomach (abdomen); respiratory tract infection; pain in the arms, hands, legs, or feet; low potassium in blood; tiredness; viral infection; cough; joint pain; dizziness; headache; and rash.

These are not all of the possible side effects of EMPAVELI. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information on pages 20-21 and see full [Prescribing Information](#), including [Boxed WARNING](#) regarding risk of serious infections, and [Medication Guide](#) for additional information.



“I love to travel. With EMPAVELI self-administration, I can bring my supplies with me and travel without interrupting my treatment schedule.”


—Emma

Emma is an adult with PNH who's taken EMPAVELI. Individual experiences may vary.

PNH=paroxysmal nocturnal hemoglobinuria.

When traveling, ensure that EMPAVELI stays between 36°F and 46°F (2°C-8°C).

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

“Self-administration means I can take EMPAVELI at home or the place that’s best for me, so I can plan my week the way I want to.”

—Peg



Peg is an adult who's taken EMPAVELI.
Individual experiences may vary.

Additional resources to help support you



Call 1-866-MY-APL-ASSIST
(1-866-692-7527)
from 8 AM-8 PM ET,
Monday-Friday



Watch the EMPAVELI
Injector Self-
administration Video at
EMPAVELI.com/taking-empaveli

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 20-22, and the full Prescribing Information and Medication Guide.

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