What is EMPAVELI?
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 can affect your immune system and can lower the ability of your immune system to fight infections.

- EMPAVELI may increase your chance of getting serious and life-threatening meningococcal infections that may quickly become life-threatening and cause death if not recognized and treated early.
- EMPAVELI may also increase the risk of getting serious infections caused by certain bacteria such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B. Serious infections may quickly become life-threatening and cause death if not recognized and treated early.
  - You must be vaccinated against these bacteria at least 2 weeks before your first dose of EMPAVELI if you have not already had these vaccines.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 16-19, and the full Prescribing Information and Medication Guide.
Find an infusion routine that works for you

This guide will provide the key steps to self-infusing EMPAVELI™ (pegcetacoplan). 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 infuse EMPAVELI the right way before you use it for the first time.

EMPAVELI is a medication you self-infuse at home or wherever is most convenient for you.

The first time you use EMPAVELI, you will be trained on how to infuse it yourself, and ongoing training will be available if you need it during treatment.

EMPAVELI infusions should be done at regular intervals twice a week or as instructed by your doctor.

The typical infusion time is about 30 minutes (if using 2 infusion sites) or about 60 minutes (if using 1 site).

Please read the Instructions for Use that came with your medication.
Step 1: Prepare your infusion

- 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
- Thoroughly clean your flat work surface using an alcohol wipe
- Wash your hands thoroughly with soap and water. Dry your hands

Step 2: Check the vial and liquid

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

Make sure your space is away from pets or small children

**DO NOT use the vial 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

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 16-19, and the full Prescribing Information and Medication Guide.
Step 3: Prepare and fill the syringe

- Remove the protective flip cap from the vial to expose the central portion of the gray rubber stopper of the vial. Throw the cap away
- Clean the stopper with a new alcohol wipe and allow the stopper to dry

To fill the syringe, you will be instructed to use either a vial adapter or a transfer needle to draw up medicine from the vial:

**OPTION 1:** If using a needleless transfer device (such as a vial adapter), follow the instructions below or the Instructions for Use provided with your vial adapter

- Remove the top cover of the vial adapter package. Do not remove the vial adapter from the package
- Attach the vial adapter to the vial. Use the blister pack to handle the vial adapter
- Connect the vial adapter to the vial by pushing it vertically down onto the vial, until the vial adapter snaps in place. Ensure the spike has penetrated the rubber stopper
- Remove the blister pack from the vial adapter and discard. Do not touch the exposed end of the vial adapter
- Attach a syringe filled with 20 mL of air to the vial adapter by turning it clockwise
- Turn the vial upside down and inject the air into the vial, which will then allow the drug to fill the syringe
- Slowly pull the plunger to fill the syringe with all the EMPAVELI™ (pegcetacoplan) liquid. Ensure all the drug is removed from the vial
- Place vial back onto flat surface and remove syringe from the vial adapter by turning counterclockwise

If using a transfer needle, see instructions on the following page

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 16-19, and the full Prescribing Information and Medication Guide.
Step 3: Prepare and fill the syringe (cont’d)

**OPTION 2:** If using a transfer needle to draw up medicine from the vial, please review the Instructions for Use that came with your medication.

- Attach a sterile transfer needle to a sterile syringe.
- Pull back the plunger to the 20-mL mark to fill the syringe with air.
- Push the air-filled syringe with transfer needle attached through the center of the vial stopper.
- The tip of the transfer needle should not be in the solution to avoid creating bubbles.
- Gently push the air from the syringe into the vial. This will inject the air from the syringe into the vial.
- Turn the vial upside down and insert the needle into the solution.
- With the transfer needle tip in the solution, slowly pull the plunger to fill the syringe with all the EMPAVELI™ (pegcetacoplan) liquid.
- Remove the transfer needle by using one hand to slide the needle into the needle cap and scoop upwards to cover the needle.
- Once the needle is covered, push the needle cap towards the syringe to fully attach it with one hand to prevent an accidental stick with the needle.
- Twist off and remove the transfer needle.
- Remove the filled syringe and the transfer needle from the vial.

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Step 4: Prepare the infusion pump and tubing

- Gather the infusion pump supplies and follow the device manufacturer’s instructions to prepare the pump and tubing.

Step 5: Prepare the infusion site(s)

- Select an area(s) on your abdomen, thighs, hips, or upper arms for the infusion(s).

- Use a different site(s) from the last time you infused EMPAVELI™ (pegcetacoplan). If there are multiple infusion sites, they should be at least 3 inches apart.

- If infusing into the abdomen, ensure that you pick a site at least 2 inches from the navel (or belly button).

- Rotate infusion sites in between each infusion.

- Clean the skin at each infusion site(s) with a new alcohol wipe, starting at the center of each infusion site and working outward in a circular motion.

- Let your skin dry.

**DO NOT** infuse into the following areas:

- Where the skin is tender, bruised, red, or hard
- Tattoos, scars, or stretch marks

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Step 6: Insert and secure the infusion needle(s)

- Pinch the skin between your thumb and forefinger around the infusion site (where you plan to insert the needle)
- Insert the needle into the skin
- Secure the needle(s) using gauze and tape or a transparent dressing placed over the infusion site(s)

Step 7: Start the infusion

- Follow the device manufacturer’s instructions to start the infusion
- The typical infusion time is about 30 minutes (if using 2 infusion sites) or about 60 minutes (if using 1 site)

Step 8: Complete the infusion

- Follow the device manufacturer’s instructions to complete the infusion

Step 9: Record the infusion

- Record your treatment in the My Infusion Tracker™ app or in another log, such as your CareKit Treatment Journal, as directed by your doctor

The My Infusion Tracker app can help you log your infusions and more. Ask your Care Coordinator to sign you up for the app.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 16-19, and the full Prescribing Information and Medication Guide.
Step 10: Clean up

- After the infusion is complete, remove the dressing and slowly take out the needle(s). Cover the infusion site(s) with a new dressing.
- Remove the infusion set from the pump and throw it away into the sharps container.
- Clean and store the infusion pump according to the device manufacturer’s instructions.

Step 11: Throw away used needles and syringes and EMPAVELI™ (pegcetacoplan) infusion tubing

- Put the used needles, syringes, and EMPAVELI infusion tubing into an FDA-cleared sharps disposal container right away after use.
- **DO NOT** throw away the used needles, syringes, and EMPAVELI infusion tubing into your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - Made of 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](http://www.fda.gov/safesharpsdisposal).
- **DO NOT** recycle your used sharps disposal container.

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INDICATION AND IMPORTANT SAFETY INFORMATION

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- EMPAVELI may increase your chance of getting serious and life-threatening meningococcal infections that may quickly become life-threatening and cause death if not recognized and treated early.
- EMPAVELI may also increase the risk of getting serious infections caused by certain bacteria such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B. Serious infections may quickly become life-threatening and cause death if not recognized and treated early.

1. You must be vaccinated against these bacteria at least 2 weeks before your first dose of EMPAVELI if you have not already had these vaccines.
2. If your healthcare provider decides that urgent treatment with EMPAVELI is needed, you should receive the required vaccinations as soon as possible.
3. If you have not been vaccinated and EMPAVELI therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
4. If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting EMPAVELI. Your healthcare provider will decide if you need additional vaccinations.
5. Vaccines reduce the risk of serious infections, but do not prevent all serious infections. 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 and a rash
   - shortness of breath
   - extreme pain or discomfort
   - headache with nausea or vomiting
   - high heart rate
   - headache and a fever
   - headache with a stiff neck or stiff back
   - confusion
   - muscle aches with flu-like symptoms
   - clammy skin
   - eyes sensitive to light

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. It is important to show this card to any healthcare provider to 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, give you a Patient Safety Card about your risk of serious infections, and make sure that you are vaccinated.

Who should NOT take EMPAVELI?
Do not take EMPAVELI if you:
- are allergic to pegcetacoplan or any of the ingredients in EMPAVELI.
- have not been vaccinated against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B, unless your healthcare provider decides that urgent treatment with EMPAVELI is needed.
- have a serious infection caused by the bacteria above.

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 final 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 final 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.

Please see full Prescribing Information, including Boxed WARNING regarding risk of serious infections, and Medication Guide for additional information.
IMPORTANT SAFETY INFORMATION (cont’d)

If you stop taking EMPAVELI™ (pegcetacoplan), 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, viral infection, and tiredness.

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 full Prescribing Information, including Boxed WARNING regarding risk of serious infections, and Medication Guide for additional information.
If you have any questions related to your infusion or need additional training on how to use EMPAVELI, we’re here to help.

Reach out to your Apellis Care Educator

Call 1-866-MY-APL-ASSIST (1-866-692-7527)

Watch the self-infusion video at www.EMPAVELI.com/how-to-take-empaveli

Schedule treatments and reminders, log your infusions, get resources, and more on the My Infusion Tracker app

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Image is an actor portrayal.