



Support you can expect when starting on EMPAVELI

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 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.

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.

Please see full Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 10-11, and the full Prescribing Information and Medication Guide.

Your path from prescription to self-administration after proper training

# Welcome to your new treatment journey with EMPAVELI® (pegcetacoplan)

This guide was designed to introduce supportive resources to help you feel ready when you start EMPAVELI. Each section outlines helpful steps you will take as you find your stride.

As always, remember that your ApellisAssist® team will be with you the whole time. Your Care Coordinator, through our specialty pharmacy, PANTHERx® Rare, and an Apellis Care Educator (ACE) are available by phone if you have any questions. It's time to take your first step! Remember, you should always talk to your doctor about any questions or concerns you may have regarding PNH or your treatment.

**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.

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# Support every step of the way

## Apellis Assist We are always at your side

#### The ApellisAssist program is designed to help you along your treatment journey

It takes teamwork to help manage PNH. The ApellisAssist patient support program provides comprehensive support, with helpful resources and experienced people dedicated to making a difference for you.

#### With the program, you have access to:



Financial assistance (for those who are eligible)



Insurance support



Self-administration training from an ACE



EMPAVELI and PNH education

#### Your ApellisAssist support partners

With EMPAVELI, you don't have to go it alone. Learn about your dedicated partners from the ApellisAssist program.



#### **Care Coordinator**

Through our specialty pharmacy, PANTHERx Rare, a Care Coordinator will:

- Help schedule your deliveries for medication and supplies
- ► Explain your insurance benefits or available financial assistance options, if eligible



### **Apellis Care Educator**

Your 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

Care Coordinators and ACEs do not give medical advice. Talk to your doctor for treatment-related questions.

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## Starting your journey

After enrolling in the ApellisAssist program, follow these straightforward steps to prepare for your first dose of EMPAVELI.

#### **Receive vaccinations**

Before starting your treatment journey with EMPAVELI, you will need to get certain vaccines. They help reduce the risk of certain serious infections.

#### **Establish insurance coverage**

If you have insurance questions, your Care Coordinator will help you figure out your coverage options. Once you are enrolled, you may be eligible for one of the financial assistance programs.

#### **Coordinate EMPAVELI delivery**

Through PANTHERx Rare, your Care Coordinator will help schedule your deliveries for medication and supplies.

#### **Complete self-administration training**

Your dedicated ACE will provide self-administration training and disease education. It's up to you to decide if you prefer in-person or virtual self-administration training.

#### **Get familiar with your CareKit by Apellis™**

When your first delivery of EMPAVELI arrives, you'll also receive a CareKit containing:

- ▶ Treatment supplies such as alcohol wipes, gauze, and adhesive bandages
- ▶ CareKit Treatment Journal
- ▶ EMPAVELI Treatment Brochure

- ▶ EMPAVELI Injector Placemat
- Your choice of\*:
- A blanket or Buzzy®
- Socks or neck wrap

\*You will be able to choose your items with your ACE.





# Integrating treatment into your life



# HOME SUITE HOME has tools to help you stay organized, store your medication, and get comfortable in your own space

You will have access to these tools once you enroll in the ApellisAssist program, but they are not a requirement. You can ask your ACE to help you order these tools at any time. We hope that you will find them to be a helpful addition to your treatment journey.



### **My Infusion Studio**

#### A case to simply stow away all of your treatment supplies

The portable My Infusion Studio has useful features and compartments to store your non-refrigerated treatment supplies so you can make your self-administration experience more convenient wherever you go!



### **Refrigerator storage**

#### A secure storage solution for your medication cartons

The refrigerator storage is designed so you can safely store and lock vial cartons of your medication in the fridge. You can use it to keep your medication separate from food, but still have easy access!



## **Travel bag**

#### A cooler to keep your medication at the right temperature

When you're on the go, it's important to always keep your medication cool. The travel bag keeps your vials at the right temperature (36°F-46°F [2°C-8°C]) when on the go for up to 19 hours.



#### **HSH TV**

#### **Expert advice on storage and comfort from an interior designer**

Genevieve Gorder shares her unique design tips and insights into storage solutions for your treatment supplies. Learn how to jump-start your routine and set up your space so that you're more comfortable when taking your medication.

Head over to <u>ApellisHSH.com</u> to watch the videos and access more resources!



# Building a routine means more control of your schedule

## Find a self-administration strategy that works best for you

You can stay on track with your treatment schedule by following these suggestions:



Establish a shipment schedule so you won't have to break your routine for low supplies or late/missing deliveries



Pick the same time to take your EMPAVELI on scheduled days— this can help you get into a consistent groove



Set up reminders on your phone to help you stay on top of your treatment schedule and appointments with your healthcare provider



Ease into a weekly routine with the administration, perhaps during a favorite show or program

Please read the <u>Instructions for Use</u> that came with your medication

# Travel with less worry



# As you start to pack for your trip, you can use this helpful checklist to gather the necessary supplies

For each time you self-administer using the EMPAVELI Injector, you'll need:



1 single-dose vial individually packaged in its original carton

- Keep vials in their outer cartons to protect against light and breakage



1 EMPAVELI Injector device



1 sterile 20 mL syringe



1 needleless transfer device (eg, vial adapter)



Alcohol wipes

#### You'll also need:



Ice pack(s) and cooler to keep medication stored at 36°F to 46°F (2°C-8°C)



Sharps container



Patient Safety Card

If provided an infusion pump for taking your EMPAVELI, talk to your ACE about different supplies that may be needed



## Keep your signed Travel Letter with you when traveling

This Travel Letter explains PNH and the supplies you need for self-administering EMPAVELI. Presenting this letter to customs and security officials will help ensure you move through security easily.

Download your Travel Letter at <a href="EMPAVELI.com/resources-and-tools">EMPAVELI.com/resources-and-tools</a>



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# Help is never far away as you find your stride on EMPAVELI® (pegcetacoplan)

## Contact...



#### **Your Care Coordinator**

Call: 1-866-MY-APL-ASSIST (1-866-692-7572)

## When you have...

- Ouestions about insurance
- Questions about delivery, late delivery, or need to reschedule
- ▶ No vials or low on vials
- Missing or lost supplies



Contact your ACE directly or call: 1-866-MY-APL-ASSIST (1-866-692-7572)

- Questions around the self-administration process
- ▶ Questions to better understand PNH



**Your Healthcare Team** 

- Questions about your PNH care, treatment, dose, or side effects
- ▶ Questions about EMPAVELI Risk Evaluation and Mitigation Strategy (REMS), vaccinations, or Patient Safety Card
- ▶ Travel questions and/or need to sign your Travel Letter



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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 lifethreatening 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

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 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.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

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.

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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.

Please see full <u>Prescribing Information</u>, including Boxed WARNING regarding risk of serious infections, and the Medication Guide for additional information.







Learn more about EMPAVELI and the ways the ApellisAssist team can support you during treatment at <a href="EMPAVELI.com">EMPAVELI.com</a>

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