

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 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.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 12-15, and the full <u>Prescribing Information</u> and <u>Medication Guide</u>.

Whether you're traveling for business or pleasure, EMPAVELI can travel with **you**.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections,

on pages 12-15, and the full Prescribing Information

and Medication Guide.

Now that you've been prescribed EMPAVELI, you might be thinking about the possibilities of self-administering on the go and traveling with your medication.

This guide has what you need to help you with preparing, packing, and, most importantly, relaxing. Read through it to get ready for your upcoming trip.

Remember, even when you travel, your ApellisAssist® team is with you every step of your journey. Your Care Coordinator, through our specialty pharmacy, PANTHERX® Rare, and Apellis Care Educator are available by phone if you have any questions. Remember, you should always talk to your healthcare provider about any questions or concerns you may have regarding PNH or your treatment.



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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Planning ahead for your destination

What supplies and documents will I need to pack for my trip?

As you start to pack for your trip, you can use the checklist on the right to gather the supplies you will need for taking EMPAVELI.

To be sure you have enough supplies for the duration of your trip, pack based on how many times you will need to self-administer your treatment while you're away. It's also a good idea to pack an extra dose just in case.

Remember to speak with your healthcare provider about your upcoming travel plans. If you plan on traveling internationally, reach out to your Care Coordinator 2 to 3 weeks before you travel to ensure you have any information you may need.



If you're traveling domestically, call your Care Coordinator to see if they can have medication shipped to your destination

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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 sterile 20 mL syringe
- 1 needleless transfer device (vial adapter)
- **⋘** 1 EMPAVELI Injector
- **⊘** Alcohol wipes



Using an infusion pump?

If so, you may need different supplies for self-administering EMPAVELI. Refer to the Instructions for Use that came with your medication

You'll also need:

- ✓ Ice pack(s) and cooler to keep medication stored between 36°F and 46°F (2°C-8°C)
- **⊘** Sharps container
- Patient Safety Card

Keep your Travel Letter, signed by your healthcare provider, with you when traveling.

The Travel Letter explains PNH and the supplies you need to treat it. Presenting this letter to customs and security officials, along with your prescription, can help ensure you move through security easily.





Handling and storing EMPAVELI while you're on the go



How should I pack EMPAVELI when traveling to my destination?

Take extra care while packing EMPAVELI and when moving from place to place.

- ▶ When traveling, ensure that EMPAVELI stays between 36°F and 46°F (2°C-8°C). Talk to your Care Coordinator for options on how to do this
- Keep the vials in their carton to protect against light and breakage
- When you're in transit or away from refrigeration, keep your medication somewhere close, where the temperature is regulated (even if ice packs are used). Remember, your medication should not be left alone
- ▶ EMPAVELI cannot be stored in checked luggage and should be hand-carried at all times for safekeeping



How will I refrigerate EMPAVELI when I arrive at my destination?

Refrigeration keeps EMPAVELI at a safe temperature, between 36°F and 46°F (2°C-8°C). Consider the tips below to help you refrigerate EMPAVELI while traveling:

- ▶ Some destinations may not have a refrigerator. Call ahead to ensure you'll have secure access to one that will be able to store your vials inside of it at the right temperature
- ▶ Sometimes freezers can be mistaken as refrigerators. Double-check or ask for help if you're unsure
- ▶ Some hotels use key cards that provide electricity to the room. Make sure removing the key card when leaving your hotel room doesn't turn off the power to the refrigerator

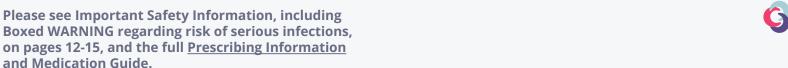


Ask about the Travel Bag!

If you have not yet received one, ask your ApellisAssist team about the Travel Bag, which keeps your medication at the right temperature for up to 19 hours.



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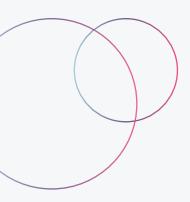


Helpful tips for a smooth experience when you're on the go



Notify your care team before you leave

▶ Inform your healthcare provider and pharmacist of your travel plans and have your healthcare provider fill out your Travel Letter. Remember, your Travel Letter only needs to be signed by your healthcare provider one time. You do not need a newly signed Travel Letter every time you travel



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Streamline your security checks at airports

- ► Have your signed Travel Letter easily accessible so you won't have to search your bags when you need it
- ► Remember, medications are generally exempt from TSA liquid rules
- ▶ Please visit the TSA website for further details, including information about volume limits



Consider an alternative disposal container if a sharps container is not available

- ➤ The Filling Base with the syringe still attached, used alcohol wipes, and packaging can be thrown away as regular trash
- If you are not able to travel with a sharps container, use another hard, puncture-proof container
- ▶ Please visit the FDA website for further information regarding sharps disposal containers



Helpful tips for a smooth experience when you're on the go (cont'd)



Reestablish your routine at your destination

EMPAVELI can be self-administered when you travel, as long as you can follow the same step-by-step instructions you follow at home.

- ▶ Once you arrive, identify a comfortable, safe place where you will self-administer your EMPAVELI
- ▶ Reestablish your routine so you can stick to a regular schedule, especially if you're staying long term

Additional information about self-administering EMPAVELI can be found in the <u>Instructions for Use</u> that came with your medication

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1080 mg/20 mL solution

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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 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.

IMPORTANT SAFETY INFORMATION (cont'd)

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

- 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.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 14-15, and the full <u>Prescribing Information</u> and <u>Medication Guide</u>.



IMPORTANT SAFETY INFORMATION (cont'd)

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.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-thecounter 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.

IMPORTANT SAFETY INFORMATION (cont'd)

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, including Boxed WARNING regarding risk of serious infections, on pages 12-13, and the full <u>Prescribing Information</u> and <u>Medication Guide</u>.







Support is never too far away



Reach out to your Care Coordinator and/or Apellis Care Educator. Call 1-866-MY-APL-ASSIST (1-866-692-7527)



Reach out to your healthcare provider for questions about your care, treatment, your dose, or side effects

Watch the instructional video at www.EMPAVELI.com/taking-empaveli

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