

INDICATIONS 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).
- ▶ adults and children 12 years of age and older with a kidney disease called complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce levels of protein in the urine (proteinuria).

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.
- 2. If you have not completed your vaccines and EMPAVELI must be started right away, you should receive the required vaccines as soon as possible.



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



Now that you've been prescribed EMPAVELI, consider the possibilities of self-administering on the go and traveling with your medication on your terms.

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 partner, 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 your diagnosis or treatment.



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

ApellisAssist can also connect you to a pharmacist who is on call 24 hours a day.





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



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

Y Patient Safety Card

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

The Travel Letter outlines the supplies you need for your treatment. Presenting this letter to customs and security officials, along with your prescription, can help ensure you move through security easily.



Download your Travel Letter at EMPAVELI.com



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







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're 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)



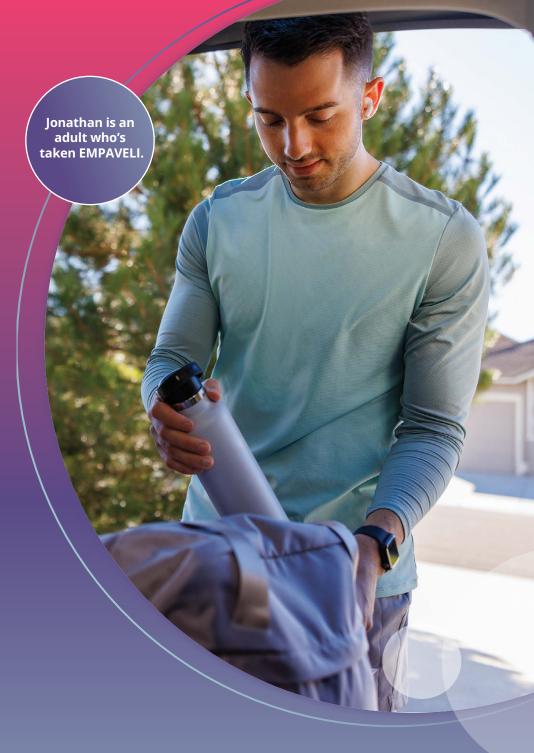
Reestablish your routine at your destination

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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- 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.
- 2. If you have not completed your vaccines and EMPAVELI must be started right away, you should receive the required vaccines as soon as possible.
- 3. 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.
- 4. 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.



IMPORTANT SAFETY INFORMATION (cont'd)

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

- 5. 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

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.

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 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 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.

If you have PNH and 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)



IMPORTANT SAFETY INFORMATION (cont'd)

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 and can be lifethreatening. Stop your EMPAVELI infusion and 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
- wheezing
- swelling of your face, tongue, or throat hives, and itching
- feel dizzy or faint or pass out

- fast heart rate
- nausea or vomiting
- ▶ feel confused or anxious
- skin reactions, including rash, hives, and itching

The most common side effects in adults 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.

The most common side effects in adults and children 12 years of age and older with C3G or primary IC-MPGN treated with EMPAVELI include injection-site reactions, fever, common cold, flu, cough, and nausea.

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.



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

Visit <u>EMPAVELI.com</u> for more resources and support options

