

Frequently Asked Questions (FAQs)

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What is EMPAVELI?

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

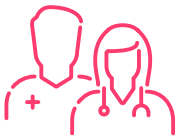
What is the most important information I should know about EMPAVELI?

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 12-14, full [Prescribing Information](#), and [Medication Guide](#).

Whether you have just started EMPAVELI or if you're considering treatment with EMPAVELI, you may have questions. Below are some frequently asked questions (FAQs) to help you during treatment. Remember, you should always talk to your doctor about any questions or concerns you may have on PNH or its treatment



Talking to your doctor about EMPAVELI

How can I talk to my doctor to find out if EMPAVELI is right for me?

Every appointment with your doctor is an opportunity to take steps toward better health. When you schedule your appointment, it's helpful to:

- ▶ Start by letting the office staff know that you would like to discuss EMPAVELI as a potential treatment option for paroxysmal nocturnal hemoglobinuria (PNH). That way, your doctor can be prepared to discuss this with you and make sure there is enough time scheduled for your appointment
- ▶ Bring a list of your symptoms, any current medications, and any other concerns you want to discuss
- ▶ Bring someone with you who can take notes about your conversation with your doctor

What are some of the benefits of EMPAVELI?

There are a number of benefits that EMPAVELI may provide:

- ▶ Improvement in hemoglobin (Hb) levels—Compared to the beginning of the PEGASUS study, people taking EMPAVELI had a 2.37 gram/dL increase in Hb level and people taking eculizumab had a 1.47 gram/dL decrease in Hb resulting in EMPAVELI showing a superior 3.84 gram/dL overall difference in Hb levels vs eculizumab ($P < 0.0001$)

To learn more about the benefits of EMPAVELI, visit www.EMPAVELI.com/clinical-trials.

What are the risks of EMPAVELI?

EMPAVELI can cause serious side effects. In partnership with your healthcare team, proper preparation may help you manage these side effects.

EMPAVELI is a medicine that can affect your immune system. EMPAVELI can lower the ability of your immune system to fight infections.

- ▶ EMPAVELI may increase your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 12-14, full [Prescribing Information](#), and [Medication Guide](#).



Talking to your doctor about EMPAVELI (cont'd)

- ▶ EMPAVELI may also increase the risk of getting serious infections. People who take EMPAVELI may have an increased risk of getting infections caused by *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
- ▶ 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
- ▶ 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
- ▶ Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all of the possible side effects of EMPAVELI. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

Serious adverse reactions were reported in 17% of patients treated with EMPAVELI:

- ▶ The most common serious adverse reaction was infections (5%)

Your doctor 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.

These are not all of the possible side effects of EMPAVELI. For more information, ask your healthcare provider or pharmacist.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 12-14, full Prescribing Information, and Medication Guide.



Talking to your doctor about EMPAVELI (cont'd)

How does EMPAVELI work?

The complement cascade is a part of your immune system that protects your body from threats like viruses or bacteria. It is responsible for both kinds of hemolysis: intravascular and extravascular.

In the complement cascade, the C3 protein binds to your PNH red blood cells and tags them for destruction, activating C5 and causing IVH. PNH red blood cells that are not destroyed through IVH continue to be covered with C3 proteins, causing EVH.

EMPAVELI works higher in the complement system than other treatments, like eculizumab. It prevents C3 from splitting into C3a and C3b, helping to stop IVH and EVH. C5 treatments, like eculizumab, work on C5.

Who can I go to with questions before I am prescribed EMPAVELI?

Before you're prescribed EMPAVELI, you should direct all questions to your doctor. Your doctor will be able to help answer questions, share information, and connect you to additional resources.

Your doctor will be your primary contact before and after you're prescribed EMPAVELI. After you have been prescribed EMPAVELI in your doctor's office, you will have the opportunity to opt in to ApellisAssist™, a patient support program. Once you are enrolled in ApellisAssist, you will have access to a dedicated Care Coordinator through our specialty pharmacy, PANTHERx Rare. You will also have access to an Apellis Care Educator, who will provide self-infusion training and disease education.



Starting on EMPAVELI

Who will be contacting my insurance provider?

Once your doctor submits the EMPAVELI Start Form with your prescription, your dedicated Care Coordinator through our specialty pharmacy, PANTHERx Rare, will work with your doctor on the approval process.

How will I know if I am approved by my insurance provider?

Based on your stated communication preferences, your Care Coordinator will communicate updates related to insurance approval.

What will my out-of-pocket costs be while taking EMPAVELI?

Out-of-pocket costs vary based on individual insurance coverage. Your Care Coordinator will help explain your insurance benefits and coverage options and review available financial assistance programs for which you may be eligible.

What is a specialty pharmacy?

You will most likely receive EMPAVELI from our specialty pharmacy, PANTHERx Rare. A specialty pharmacy provides medications used to treat rare diseases or more complex health problems. Many of these medications are not stocked by regular pharmacies.

The staff at specialty pharmacies are trained to help you understand your medication better. They will also communicate with your healthcare team and insurance company whenever necessary.

How do I get my medication and everything I need to self-infuse?

Medication and supplies will typically be shipped by PANTHERx Rare on a monthly basis to a location of your choice. If you choose to enroll in ApellisAssist, you'll receive a CareKit containing everything you need to get acquainted with self-infusion.

How will I know if my medication will be delivered securely?

Your Care Coordinator will work with you to schedule shipments on the delivery date and at the location of your choice. Someone will need to be available to sign for delivery upon arrival.

EMPAVELI must be stored in the refrigerator in the original cartons, between 36 °F and 46 °F (2 °C and 8 °C), once delivered.

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 12-14, full [Prescribing Information](#), and [Medication Guide](#).



Self-infusion training and ApellisAssist

How do I get trained to infuse my own medication?

A qualified healthcare professional can show you or your caregiver how to infuse EMPAVELI correctly before you use it for the first time. You and your doctor can decide the best option for training you on how to use EMPAVELI. You may decide to work with an Apellis Care Educator or receive training from your healthcare provider at your appointment. Your Care Educator is a compassionate partner with a nursing background who will provide you with self-infusion training, education, and ongoing EMPAVELI support.

How do I enroll in ApellisAssist?

If you are unsure whether you are enrolled in ApellisAssist, or if you would like to enroll, call **1-866-MY-APL-ASSIST** (1-866-692-7527) and your Care Coordinator will confirm or assist you with enrollment.

How does my Care Educator contact me and how do we communicate?

As you prepare to start on EMPAVELI, you will collaborate with your Apellis Care Team, comprised of a dedicated Care Coordinator through our specialty pharmacy, PANTHERx Rare, and a Care Educator. Together, you'll make decisions on your communication preferences, such as:

- ▶ In-home or telehealth infusion training
- ▶ Preferred communication style
- ▶ Frequency of calls or text reminders

All of this is designed to prepare you for a seamless start and give you confidence on your treatment journey.

Your Care Coordinator will work with you one-on-one to help address your insurance, financial, and logistical questions around EMPAVELI. Your Care Educator is here to help you with things like self-infusion training, education, and ongoing EMPAVELI support.

Who can I call for additional help regarding my treatment?

Your doctor will be your primary contact before and after you're prescribed EMPAVELI.

Once you are enrolled in ApellisAssist, you will have access to a dedicated Care Coordinator through our specialty pharmacy, PANTHERx Rare. You will also have access to a Care Educator, who will provide self-infusion training and disease education.



Taking EMPAVELI

How long can I store EMPAVELI in my refrigerator?

EMPAVELI can be used until the expiration date printed on the carton. Do not use EMPAVELI if the expiration date has passed.

At what temperature does it need to be stored?

EMPAVELI should be stored in the refrigerator between 36°F and 46°F (2°C and 8°C) in the original carton to protect from light.

How long do I need to warm up the vial before starting my infusion?

Once you remove a single-vial carton from the refrigerator, keep the vial in its carton and let it warm up to room temperature, which should take approximately 30 minutes. Do not try to speed up the warming process.

What do I do if the vial is unusable according to the Instructions for Use (IFU)?

You should not use the vial of medication if:

- ▶ Liquid looks cloudy
- ▶ Liquid contains particles
- ▶ Liquid is dark yellow
- ▶ Protective flip cap is missing or damaged
- ▶ Expiration date on the label has passed

If any of the above is true, set the vial aside and take another vial carton from the refrigerator. You should repeat the vial warming process and let it warm up to room temperature for approximately 30 minutes. Email the Apellis Product Compliance Team at medinfo@apellis.com to report the issue with your vial.



Taking EMPAVELI (cont'd)

What happens if my vial is broken or unusable or it is my last vial?

The liquid in the vial should be clear, colorless, or slightly yellowish. If a vial is broken, the liquid looks cloudy, has particles, or is dark yellow, you should throw it out. Also, you should not use any vial with a missing or damaged flip cap, or if the expiration date has passed.

You should take out a new vial carton from the refrigerator and repeat the warming process to infuse.

To order more EMPAVELI or schedule a delivery, reach out to your Care Coordinator through our specialty pharmacy, PANTHERx Rare.

If your vial breaks, set it aside and do not use it. Do not try to use any of the liquid from the broken vial. Email the Apellis Product Compliance Team at medinfo@apellis.com to report the issue with your vial.

When it comes time to refill your medication, PANTHERx Rare will reach out to you approximately 10 days prior to needing your refill. Be sure to accept their refill call and schedule your next shipment of medication. If you have any questions regarding refills, or if you break a vial, contact ApellisAssist at **1-866-MY-APL-ASSIST** (1-866-692-7527).

What happens if I miss a dose?

If you miss a dose of EMPAVELI, take the missed dose as soon as possible. Then take the next dose at your regularly scheduled time. Talk to your doctor and email the Apellis Product Compliance Team at medinfo@apellis.com to report if you missed a dose and the reason the dose was missed.

It is recommended that you keep a record of the doses you take in the My Infusion Tracker™ app, CareKit Treatment Journal, or other type of journal or log. Be sure to take the record with you each time you visit your doctor because they may ask to see it.

What happens if my infusion pump doesn't work?

If your infusion pump is broken and you're unable to infuse, you should call your Care Coordinator right away to order a new pump. You should also record that you missed an infusion and email the Apellis Product Compliance Team at medinfo@apellis.com to report the issue with your infusion pump.

What happens if the infusion pump breaks?

If your infusion pump breaks, follow the device manufacturer's instructions. If you need additional support, please call our specialty pharmacy, PANTHERx Rare, at **1-866-MY-APL-ASSIST** (1-866-692-7527). You should also email the Apellis Product Compliance Team at medinfo@apellis.com to report the issue with your infusion pump.

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Taking EMPAVELI (cont'd)

Can I self-infuse EMPAVELI while I'm traveling?

EMPAVELI can be self-infused when you are traveling, as long as you can follow the same step-by-step instructions you follow at home. Please talk to your doctor before you travel and refer to the Travel Guide for specific details on travel storage, preparation, packing, and tips for traveling. The Travel Guide can be found at www.EMPAVELI.com/resources.



Potential side effects of EMPAVELI

Why do I need vaccines before starting EMPAVELI?

EMPAVELI can lower the ability of your immune system to fight infections and may increase your chance 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 may cause death if not recognized and treated early. Therefore, your doctor will ensure you have been vaccinated against these bacteria. If you have not already had these vaccines, you must receive them at least 2 weeks before starting treatment with EMPAVELI.

If you have not been vaccinated and EMPAVELI therapy must be started immediately, you should also receive 2 weeks of antibiotics with your vaccinations.

Even if you have had these vaccines in the past, you might need additional vaccinations before starting EMPAVELI. Your healthcare provider will decide if you need additional vaccinations.

Vaccines reduce the risk of serious infections, but do not prevent all serious infections.

How will I know if I have a serious infection?

Call your doctor or seek emergency medical care right away if you have any new signs or symptoms of infection, or if you have 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

Remember to carry the Safety Card provided by your doctor 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 who treats you. This will help them diagnose and treat you quickly.



Potential side effects of EMPAVELI (cont'd)

What are the most common side effects associated with EMPAVELI?

The most common side effects seen in EMPAVELI clinical trials were:

- ▶ Injection-site reactions
- ▶ Infections
- ▶ Diarrhea
- ▶ Pain in the stomach (abdomen)
- ▶ Respiratory tract infection
- ▶ Viral infection
- ▶ Tiredness

Your doctor will provide specific instructions on how to handle common side effects.

These are not all the possible side effects associated with EMPAVELI. Be sure to tell your doctor about any side effect that bothers you or that you experience. In addition, call your doctor for medical advice about side effects. You may also report side effects to the FDA at 1-800-FDA-1088.

Should I stop taking EMPAVELI if I experience a side effect?

You should talk to your doctor before you stop taking EMPAVELI. Your doctor will work with you to help determine what to do, or help manage any side effects that may arise.



Additional resources

Where can I go to learn more about EMPAVELI?

For more information about EMPAVELI, visit www.EMPAVELI.com

What additional resources are available to me while on treatment?

After you're enrolled in ApellisAssist, there will be additional resources available to you.

The My Infusion Tracker™ app offers administration reminders, self-infusion timers, guides, and much more. Visit www.EMPAVELI.com/resources to learn more.

HOME SUITE HOME is a program that empowers you with tools to help you comfortably integrate self-infusions into your home. HOME SUITE HOME offers tools to stay organized and store EMPAVELI, and videos to help optimize your home space for self-infusions. Learn more by visiting www.EMPAVELI.com/resources

INDICATION AND IMPORTANT SAFETY INFORMATION

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.

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.

Please see full [Prescribing Information](#), including **Boxed WARNING regarding risk of serious infections, and [Medication Guide](#) for additional information.**

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 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.

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
- ▶ tiredness
- ▶ blood in your urine
- ▶ pain in the stomach (abdomen)
- ▶ shortness of breath
- ▶ blood clots
- ▶ trouble swallowing
- ▶ 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.

Please see full [Prescribing Information](#), including **Boxed WARNING regarding risk of serious infections, and [Medication Guide](#) for additional information.**

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of EMPAVELI? (cont'd)

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.**