

Getting your vaccinations before treatment

EMPAVELI is a medicine that affects your immune system and may lower the ability of your immune system to fight infections. Before starting your treatment journey with EMPAVELI, you will need to get certain vaccines.



What vaccines do I need?

At least 2 weeks before your first dose of EMPAVELI, complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis*.

You may need the following vaccines:

- ▶ Pneumococcal vaccination(s)
- ▶ Meningococcal vaccinations
 - ▶ MenACWY series
 - ▶ MenB series



Where can I get these vaccinations?

Start by talking to your healthcare provider to see if they offer the vaccines.

Vaccines may also be available at:

- ▶ Retail Pharmacies
- ▶ Health Clinics
- ▶ Local Health Department

Vaccination Support

Our ApellisAssist[®] team offers support to help you **obtain any vaccinations recommended before starting EMPAVELI**. Your physician can opt-in to Vaccination Support on the EMPAVELI Start Form and a dedicated team member will follow up with you to provide additional information and **discuss if you may be eligible for support**.



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.

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.**

Please see full Important Safety Information, including Boxed WARNING regarding risk of serious infections, throughout, and the full [Prescribing Information](#), and [Medication Guide](#).

Tips for getting your vaccinations



Tips when scheduling your vaccination appointment

- ▶ Notify them that you have a prescription from your healthcare provider and that you need these vaccinations to start treatment
- ▶ If there are any questions regarding the vaccinations from the provider, please ask them to call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527) from 8 AM-8 PM ET, Monday-Friday



Once you get your vaccinations

- ▶ Request a printout of vaccinations received to keep for your record
- ▶ Share your vaccination record with your healthcare provider
- ▶ Make follow-up appointments for vaccinations that are part of a multi-dose series

Have questions or need help finding vaccination providers?

Our ApellisAssist team can help. Call 1-866-MY-APL-ASSIST (1-866-692-7527) from 8 AM-8 PM ET, Monday-Friday.

IMPORTANT SAFETY INFORMATION (cont'd)

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.
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.

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Meet the ApellisAssist Team

Support every step of the way



Care Coordinator

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



Vaccine Coordinator

- ▶ Researching local pharmacies based on location and insurance coverage
- ▶ Creating a list of options with required vaccines in stock, including hours and appointment details
- ▶ Coordinating with the chosen pharmacy to transfer prescriptions and confirm billing information



Apellis Care Educator (ACE)

- ▶ Give 1-on-1 training on how to self-administer EMPAVELI – in your home or virtually
- ▶ Provide a wide variety of educational resources
- ▶ Offer ongoing support every step of the way

Care Coordinators, Vaccine Coordinators, and Apellis Care Educators do not give medical advice. Talk to your doctor for treatment-related questions.

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 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.

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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 and can be life-threatening. 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
- ▶ 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.

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