

To Whom It May Concern:

_____ is currently under my care and is being treated with a medication called EMPAVELI™ (pegcetacoplan). This requires my patient to self-administer medication I have prescribed. My patient or their caregiver will therefore be carrying one or more of the following items:

- Vials of EMPAVELI packaged in cartons
- Ice pack(s) and cooler to keep medication cold
- Infusion pump with compatible syringe
- Needleless transfer device or needle infusion set(s)
- Infusion set(s)
- May include tubing and connectors
- Sharps container
- Medical supplies, such as alcohol, wipes, and Band-Aids

Please note EMPAVELI must be kept at a certain temperature (36°F to 46°F [2°C to 8°C]) and, therefore, cannot be stored in checked luggage and should be hand carried at all times. EMPAVELI is also light sensitive, so it must be kept within its carton to prevent degradation.

Please allow my patient to pass through security and board their flight with this medication and supplies.

If you have any questions, please feel free to contact me at:

Physician's name

Physician's signature

Contact information

Date

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.

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

 **EMPAVELI™**
(pegcetacoplan) injection
1080 mg/20 mL solution

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.

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
- ▶ 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, viral infection, and tiredness.

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.



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