What is EMPAVELI™?

EMPAVELI™ (pegcetacoplan) is a prescription medicine that is used to treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH). EMPAVELI is given by infusion under the skin.

What are the serious risks of EMPAVELI?

EMPAVELI can lower the ability of your immune system to fight infections. EMPAVELI may increase the risk of getting serious infections. Serious infections may quickly become life-threatening and cause death if not recognized and treated early. These serious infections are caused by certain bacteria: *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae type B*.

Call your healthcare provider or get emergency care right away 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

Why are vaccines important?

- Vaccines lower the risk of getting serious infections. However, vaccines do not prevent all serious infections.
- Your healthcare provider will review what vaccines you have had.
- You must be vaccinated against certain bacteria at least 2 weeks before your first dose of EMPAVELI unless you have already had the vaccines.
- If your healthcare provider decides that urgent treatment with EMPAVELI is needed, you should receive the required vaccinations as soon as possible.
- If you have not been vaccinated and EMPAVELI therapy must be started right away, you should also receive 2 weeks of antibiotics with your vaccinations.
- If you have been vaccinated against certain bacteria in the past, you might need additional vaccinations before starting EMPAVELI. Your healthcare provider will decide if you need additional vaccinations.
What do I need to do before and after my treatment with EMPAVELI?

- Review the Patient Safety Guide (this document) and Patient Wallet Card.
- Receive counseling from your healthcare provider on the risk of serious infections and their possible signs and symptoms using the Patient Safety Guide and Patient Wallet Card.
- Tell your healthcare provider about what vaccines you have had.
- Get vaccines as told by your healthcare provider.
- Take antibiotics as told by your healthcare provider for 2 weeks after receiving a vaccine if EMPAVELI must be started right away.

Patient Wallet Card:

- You will receive a Patient Wallet Card from your healthcare provider.
- Carry this card at all times during treatment and for 2 months after your last EMPAVELI dose.
- Show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.
- Get treatment right away for any symptoms of serious bacterial infection even if you do not have your card on you.

At all times:

- Get immediate medical care right away if you have any of the signs of a serious infection (as shown on the page one).

What is a Risk Evaluation and Mitigation Strategy (REMS)?

A REMS is a drug safety program that the US Food and Drug Administration (FDA) requires for certain medicines with serious safety concerns. Drug companies, healthcare providers, and pharmacies must take extra steps to make sure the benefits of using the drug are greater than the risks.

Why does EMPAVELI have a REMS?

EMPAVELI has a REMS because it can increase your chance of having serious infections, which may quickly become life-threatening and cause death if not recognized and treated early. The EMPAVELI REMS was set up to make sure healthcare providers, pharmacists, and patients are aware of these serious risks.

How will I get my EMPAVELI medicine?

Only certain pharmacies can fill your EMPAVELI prescription. The pharmacies that are part of the EMPAVELI REMS will contact you to fill your prescription for EMPAVELI and ship it to your preferred address. If you have questions about the EMPAVELI REMS, you can call the EMPAVELI REMS.

Phone: 1-888-343-7073
Hours of Operation: 8:00 AM – 8:00 PM Eastern Time
www.EMPAVELIREMS.com
IMPORTANT SAFETY INFORMATION:

If you have any questions about your health or medicines, talk to your healthcare provider. To report side effects, contact the REMS Program at 1-888-343-7073 Apellis Pharmaceuticals, Inc. at 1-833-866-3346, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch