EMPAVELI™ (pegcetacoplan) Risk Evaluation and Mitigation Strategy (REMS)

Healthcare Provider Brochure

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

If you have any questions regarding the REMS, please visit www.EMPAVELIREMS.com or call 1-888-343-7073.

Please see Prescribing Information, including BOXED WARNING for serious infections caused by encapsulated bacteria, for more detailed safety information for EMPAVELI.
What is EMPAVELI™?

EMPAVELI™ (pegcetacoplan) is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

Risk of Serious Bacterial Infections Caused by Encapsulated Bacteria

- Meningococcal infections may occur in patients treated with EMPAVELI and may become rapidly life-threatening or fatal if not recognized and treated early.
- Use of EMPAVELI may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y and B, and Haemophilus influenzae type B (Hib).
- To reduce the risk of infection, all patients must be vaccinated against these bacteria according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations for patients with altered immunocompetence associated with complement deficiencies.
- Vaccinate patients against encapsulated bacteria as recommended at least 2 weeks prior to administering first dose of EMPAVELI unless the risks of delaying EMPAVELI therapy outweigh the risk of developing a serious infection.
- Provide 2 weeks of antibacterial drug prophylaxis to patients if EMPAVELI must be initiated immediately and vaccines are administered less than 2 weeks before starting therapy with EMPAVELI.
- Vaccination reduces but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate immediately if infection is suspected.

See the Prescribing Information for EMPAVELI, including BOXED WARNING, for more information on the risk of serious bacterial infection.

What is the EMPAVELI REMS?

This Risk Evaluation and Mitigation Strategy (REMS) is a safety program required by the Food and Drug Administration (FDA) to ensure the potential benefits of EMPAVELI outweigh its risks.

EMPAVELI is available only through the EMPAVELI REMS, a restricted distribution program that seeks to ensure prescribers are informed about the risk of serious infections associated with the use of EMPAVELI. Prescribers must become certified in the REMS before prescribing EMPAVELI.
What do Healthcare Providers Need to Do Before Prescribing EMPAVELI?

To enable prescribing:
Prescribers of EMPAVELI must be certified (enrolled) in the REMS to prescribe. To certify, prescribers must complete the following steps:

1: Review the EMPAVELI Prescribing Information
2: Review the Healthcare Provider Brochure (this document)
3: Review the Patient Safety Guide
4: Review the Patient Wallet Card
5: Complete and submit the Prescriber Enrollment Form to the EMPAVELI REMS

Prescribers will be notified within 2 business days when their certification in the EMPAVELI REMS is complete and they can prescribe EMPAVELI.

Before initiating a patient’s treatment:

- Assess the patient’s vaccination status for the following: *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* Type B (HiB), and immunize patient if needed according to the current ACIP recommendations for vaccinations against encapsulated bacteria in patients with altered immunocompetence associated with complement deficiencies.
- If immediate therapy with EMPAVELI is indicated, administer required vaccine as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis.
- Counsel the patient on:
  - the requirement to vaccinate patients against encapsulated bacteria.
  - How to recognize and respond to signs and symptoms of serious bacterial infection, using the Patient Safety Guide and Patient Wallet Card.
- Provide the patient with the Patient Safety Guide and Patient Wallet Card.

During a patient’s treatment:

- Assess patients for early signs and symptoms of serious infection and treat patients immediately if an infection is suspected.
- Consider discontinuation of EMPAVELI in patients who are undergoing treatment for serious bacterial infection.
- Revaccinate patients in accordance with ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies.

At all times:

- Report cases of serious bacterial infection, including the patient’s clinical outcomes, to Apellis Pharmaceuticals, Inc.
- Comply with the requirements of the EMPAVELI REMS to maintain certification to prescribe.
- Comply with requests from the EMPAVELI REMS and its agents or contractors to support the administration of the EMPAVELI REMS.
What do Pharmacists Need to Do to Dispense EMPAVELI?

To enable dispensing:
EMPAVELI may only be dispensed by pharmacies that are certified to dispense. To become certified, the pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. For a pharmacy to become certified, the Authorized Representative must complete the following steps:

**STEP 1:** Review the Healthcare Provider Brochure (this document)

**STEP 2:** Complete and submit the Pharmacy Enrollment Form to the EMPAVELI REMS

By completing the Pharmacy Enrollment Form, the Authorized Representative agrees that s/he has:
- Reviewed the Healthcare Provider Brochure.
- Completed the Pharmacy Enrollment Form and submitted it to the EMPAVELI REMS.
- Agreed to train all relevant staff involved in dispensing EMPAVELI using the Healthcare Provider Brochure.
- Establish processes and procedures to contact the prescriber to assess the patient’s vaccination history including antibiotic prophylaxis and document the findings.

Before dispensing, the Authorized Representative will ensure that all pharmacy staff must:
- Obtain authorization to dispense each prescription by contacting the EMPAVELI REMS online or by calling the REMS Coordinating Center to verify the prescriber is certified.
- Assess the patient’s vaccination history including antibiotic prophylaxis by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the EMPAVELI REMS.

On behalf of the pharmacy, the Authorized Representative will comply with the following EMPAVELI REMS requirements:
- Report adverse events of serious bacterial infections to Apellis Pharmaceuticals, Inc.
- Not distribute, transfer, loan or sell EMPAVELI, except to certified dispensers.
- Maintain records documenting staff’s completion of training.
- Maintain records that all EMPAVELI REMS processes and procedures are in place and being followed.
- Comply with audits carried out by Apellis Pharmaceuticals, Inc. or third party acting on behalf of Apellis Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense:
- Any new Authorized Representative must enroll in the EMPAVELI REMS by completing the Pharmacy Enrollment Form and submitting it to the EMPAVELI REMS.
Adverse Event Reporting:
Healthcare Providers should report all adverse events including those of serious bacterial infection by contacting Apellis Pharmaceuticals, Inc. at 1-833-866-3346 or the FDA at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

EMPAVELI REMS Resources
For more information about the EMPAVELI REMS, visit www.EMPAVELIREMS.com or call the EMPAVELI REMS at 1-888-343-7073.
The below resources are available for download at www.EMPAVELIREMS.com.

Prescriber
- Prescribing Information
- Healthcare Provider Brochure (this document)
- Prescriber Enrollment Form

Pharmacy
- Healthcare Provider Brochure (this document)

Patient
- Medication Guide
- Patient Safety Guide
- Patient Wallet Card
This guide does not provide complete safety information on EMPAVELI. Please see Prescribing Information, including BOXED WARNING for serious infections caused by encapsulated bacteria, for complete safety profile of EMPAVELI.