

MEDICATION GUIDE
EMPAVELI® (em-puh-vel-ee)
(pegcetacoplan)
injection, for subcutaneous use

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

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

- **EMPAVELI increases your chance of getting serious infections caused by encapsulated bacteria, including *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.**
 - 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.
 - If you have not completed your vaccines and EMPAVELI must be started right away, you should receive the required vaccines as soon as possible.
 - 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.
 - 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.
 - 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 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 dose of EMPAVELI. 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
- give you a **Patient Safety Card** about your risk of serious infections, as discussed above

For more information about side effects, see **“What are the possible side effects of EMPAVELI?”**

What is EMPAVELI?

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

It is not known if EMPAVELI is safe and effective in children.

Do not take EMPAVELI if you:

- are allergic to pegcetacoplan or any of the ingredients in EMPAVELI. See the end of this Medication Guide for a complete list of ingredients in EMPAVELI.
- have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *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.

- Females who are able to become pregnant should use an effective method of birth control (contraception) 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 medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. EMPAVELI and other medicines can affect each other, causing side effects.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take EMPAVELI?

- **See the detailed Instructions for Use that comes with your EMPAVELI for information about how to prepare and infuse your dose of EMPAVELI with your infusion pump.**
- **See the detailed Instructions for Use that comes with your EMPAVELI Injector for information about how to prepare and inject your dose of EMPAVELI with your EMPAVELI Injector.**
- Your healthcare provider should show you how to prepare and administer EMPAVELI before you use it for the first time.
- Use EMPAVELI exactly as your healthcare provider tells you. Do not use more or less than your healthcare provider tells you to.
- EMPAVELI is given under the skin (subcutaneously) 2 times each week. If there is an increase in your LDH, an enzyme in your blood, your healthcare provider may tell you to take EMPAVELI every 3 days.
- **If you are changing treatment from eculizumab to EMPAVELI, you should continue eculizumab for 4 weeks after your first dose of EMPAVELI. After 4 weeks, you should stop treatment with eculizumab.**
- **If you are changing treatment from ravulizumab to EMPAVELI, you should take your starting dose of EMPAVELI no more than 4 weeks after your last dose of ravulizumab.**
- **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.**

Symptoms or problems that can happen due to red blood cell breakdown include:

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| ○ 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) |

If you miss a dose of EMPAVELI, take the missed dose as soon as possible. Take your next dose at your regularly scheduled time.

What are the possible side effects of EMPAVELI?

EMPAVELI can cause serious side effects including:

- See **“What is the most important information I should know about EMPAVELI?”**
- **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	○ fast heart rate
○ trouble breathing or shortness of breath	○ nausea or vomiting
○ wheezing	○ feel confused or anxious
○ swelling of your face, tongue, or throat	○ skin reactions, including rash, hives, and itching
○ feel dizzy or faint or pass out	

The most common side effects in people with PNH treated with EMPAVELI include:

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| • injection-site reactions | • tiredness |
| • infections | • viral infection |
| • diarrhea | • cough |
| • pain in the stomach (abdomen) | • joint pain |
| • respiratory tract infection | • dizziness |
| • pain in the arms, hands, legs or feet | • headache |
| • low potassium in blood | • rash |

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.

How should I store EMPAVELI?

- Store vials of EMPAVELI in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- Do not use EMPAVELI past the expiration date stamped on the carton.

Keep EMPAVELI and all medicines out of the reach of children.

General information about the safe and effective use of EMPAVELI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use EMPAVELI for a condition for which it was not prescribed. Do not give EMPAVELI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about EMPAVELI that is written for health professionals.

What are the ingredients in EMPAVELI?

Active ingredient: pegcetacoplan

Inactive ingredients: sorbitol, glacial acetic acid, sodium acetate trihydrate, Water for Injection USP. EMPAVELI may also contain sodium hydroxide and/or additional glacial acetic acid for pH adjustment.

Manufactured for:

Apellis Pharmaceuticals, Inc. 100 Fifth Avenue Waltham, MA 02451

For patent information: www.apellis.com/productpatent

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For more information, go to www.EMPAVELI.com or call 1-866-692-7527

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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