

 **EMPAVELI**[®]
(pegcetacoplan) injection
1080 mg/20 mL solution

If you're like Angelo, an adult
with PNH taking EMPAVELI,

Where will you go next?

Talk to your doctor about whether
EMPAVELI is right for you.



What is the **EMPAVELI**
Injector all about?

Find out more inside!

PNH=paroxysmal nocturnal hemoglobinuria.

INDICATION 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).

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 additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.



Explore the compact, wearable EMPAVELI Injector!

The EMPAVELI Injector allows you to self-administer your EMPAVELI when and where works best for you (after receiving proper training).

Each EMPAVELI injection should take approximately 30 to 60 minutes.



[glow-bin]

verb; Acting in pursuit of higher hemoglobin levels

Globin' can correlate to higher levels of hemoglobin in your blood. Hemoglobin carries oxygen throughout your body—and oxygen is, you know, the stuff of life. If you're intrigued by what higher hemoglobin levels could mean for you, ask your doctor about EMPAVELI.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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PNH=paroxysmal nocturnal hemoglobinuria.

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The impact of hemolysis in PNH

Ongoing hemolysis may be causing your PNH symptoms



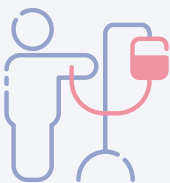
Paroxysmal nocturnal hemoglobinuria (PNH) is a rare blood disease that involves the body's immune system acting irregularly.

In PNH, the immune system attacks and destroys its own red blood cells in a process called hemolysis.



If hemolysis is not addressed, it can cause lower than normal levels of red blood cells and hemoglobin (Hb) in your blood.

This may cause ongoing PNH symptoms, like fatigue, that force you to make compromises in your daily life.



Also, with anemia caused by low Hb levels, people with PNH may need to get frequent transfusions, which can take a toll on the body over time.

Findings from a US survey of people with PNH taking C5i treatment

- 122 people taking a C5i treatment for their PNH were surveyed (35 received eculizumab, 87 received ravulizumab)
- Most people surveyed (97%) had been taking C5i treatment for ≥ 3 months

Possible limitations of the survey

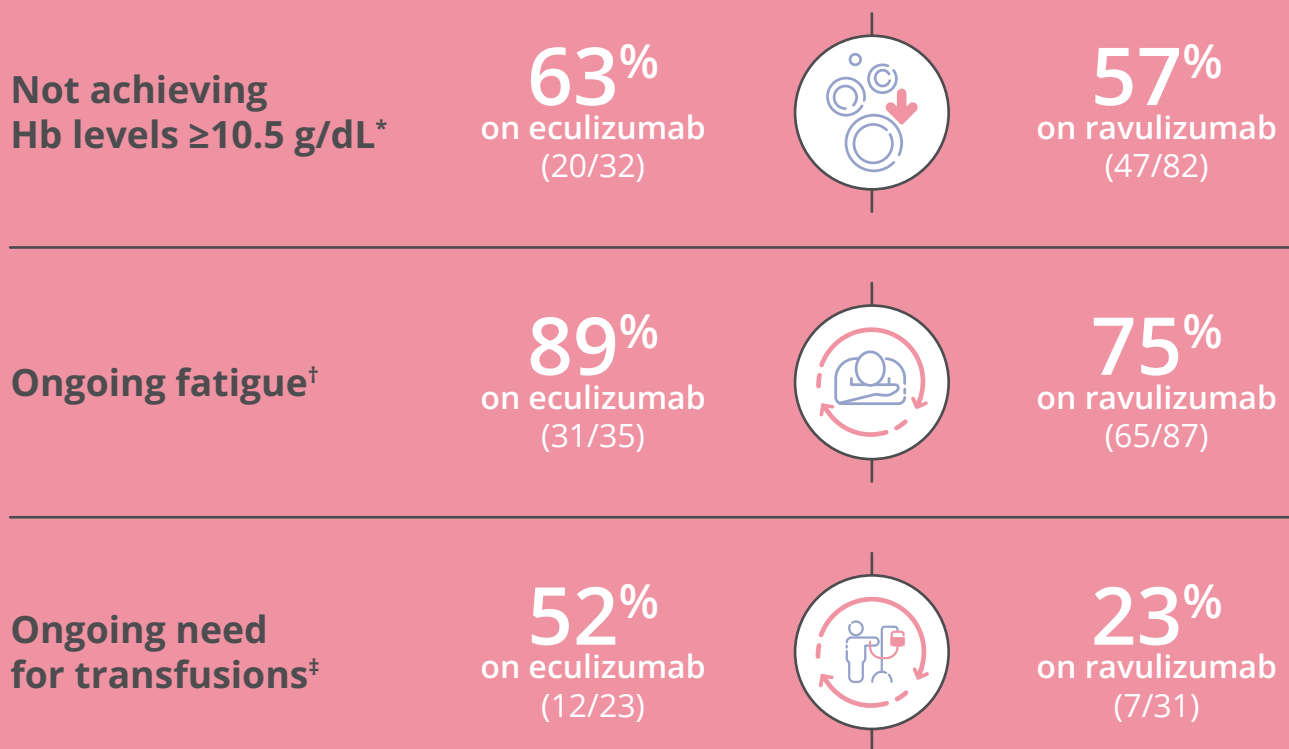
- A small number of people surveyed
- People not satisfied with their current C5i treatment may have been more motivated to participate
- Responses being subjective due to how people interpreted and reported their experiences
- The results cannot be generalized to all people with PNH

With C5i treatments, some people with PNH may continue to have symptoms

According to this survey, some people continued to have low Hb levels, ongoing fatigue, and the need for transfusions.

This could mean hemolysis is not under control.

In this survey, people reported:



C5i=C5 inhibitor.

*Based on responses from 114 of the 122 survey participants who reported their Hb levels.

†Fatigue was measured using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) scale, which is a type of survey that collects information about the impact of fatigue on different parts of daily life. The scale ranges from 0 to 52. Higher scores mean less fatigue.

‡In patients who had a lifetime history of a transfusion and were on C5i treatment for at least 1 year. The need for transfusions was defined as 1 or more transfusions in the past 12 months.

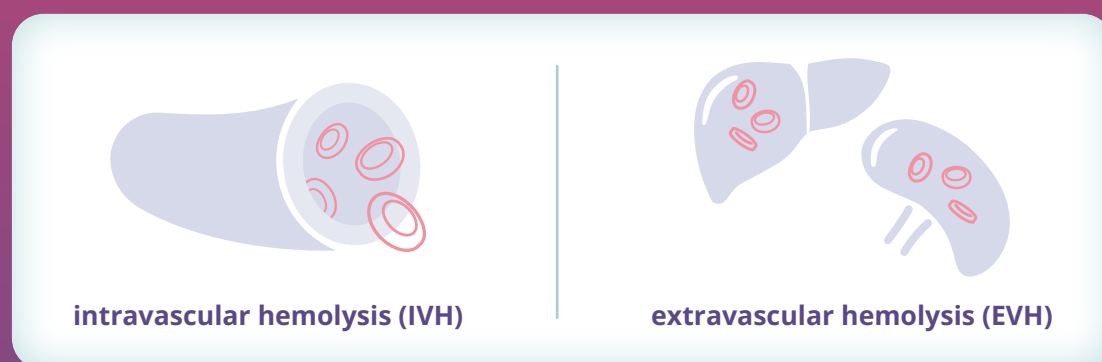


Don't delay!

Talk to your healthcare provider about your ongoing PNH symptoms and available treatment options.

How EMPAVELI works in PNH

EMPAVELI is the first and only C3i treatment for PNH that controls both types of hemolysis



The complement system is a part of your immune system and helps the body fight off infections. Certain proteins in the complement system work together and create a chain reaction.

This chain reaction is called the complement cascade.

C3i=C3 inhibitor.

IMPORTANT SAFETY INFORMATION (cont'd)

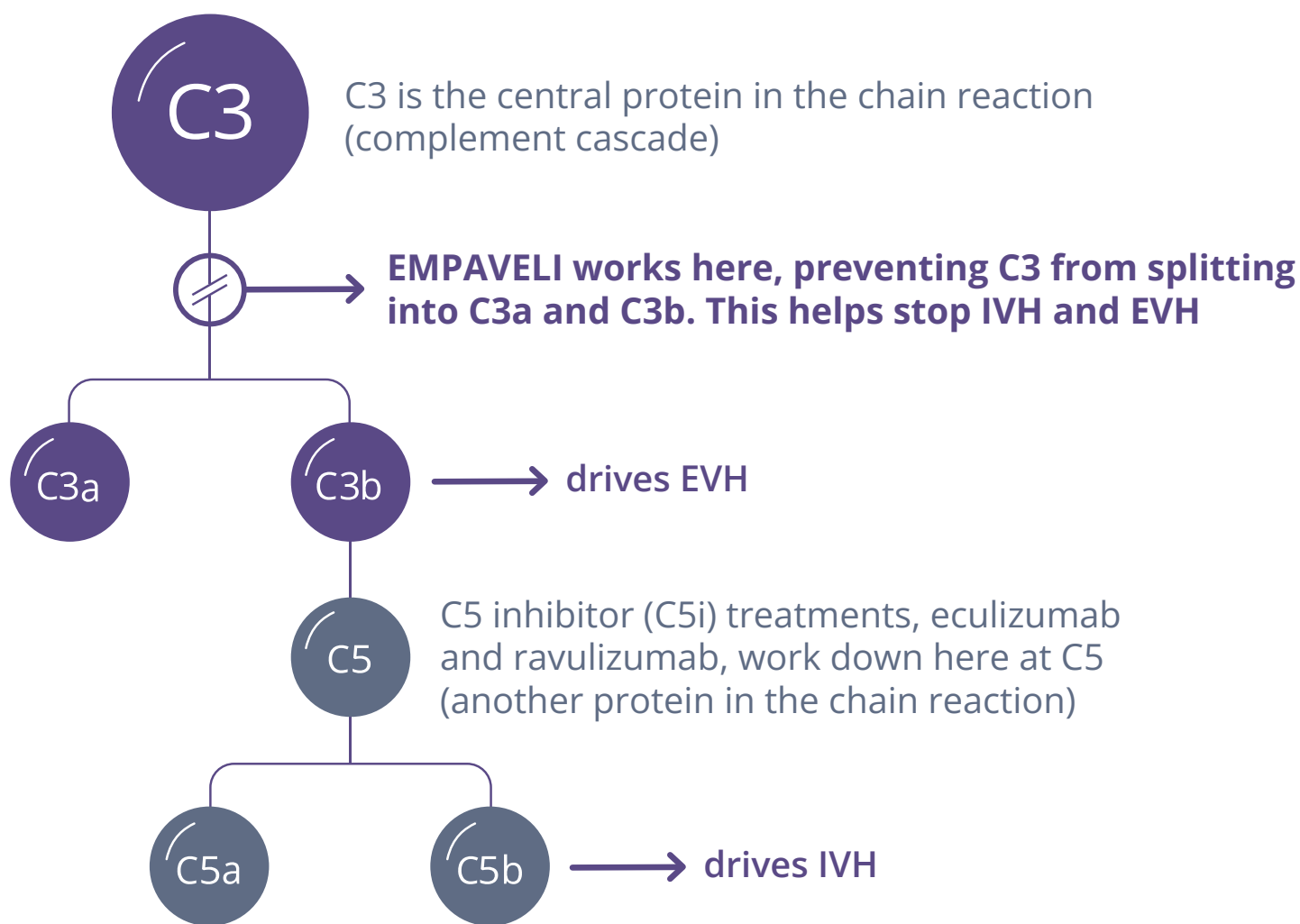
What is the most important information I should know about EMPAVELI? (cont'd)

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

EMPAVELI acts differently than other PNH treatments

EMPAVELI works higher in the complement system than C5i treatments



PNH=paroxysmal nocturnal hemoglobinuria.

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How EMPAVELI was studied

EMPAVELI was studied in two Phase 3 clinical trials for PNH:

- ▶ The PEGASUS study, which included adults with previous C5i treatment (eculizumab)
- ▶ The PRINCE study, which included adults without any previous complement inhibitor treatment

See how EMPAVELI was studied in PEGASUS

In the PEGASUS clinical trial, EMPAVELI was compared to the C5i treatment eculizumab



80 adults
with PNH



On a steady dose
of **eculizumab** for
at least 3 months



With low hemoglobin
(Hb) levels
(less than 10.5 g/dL)

The study consisted of 3 parts:



Part 1

All participants received both eculizumab and EMPAVELI



Part 2

They were then split into 2 groups:

- ▶ Group 1 received only EMPAVELI for 16 weeks (n=41)
- ▶ Group 2 received only eculizumab for 16 weeks (n=39)



Part 3

- ▶ Group 1 continued EMPAVELI for 32 more weeks
- ▶ Group 2 transitioned to EMPAVELI for 32 weeks*

*The transition time for Group 2 was 4 weeks and involved taking both eculizumab and EMPAVELI, before receiving EMPAVELI only.

Main goals of PEGASUS

- ▶ Primary goal: explore changes in Hb levels from the beginning of the study
- ▶ Safety: monitor the occurrence of side effects

Selected secondary goals and analyses

- ▶ See how many people could become transfusion-free[†]
- ▶ Explore changes in absolute reticulocyte count (ARC) from the beginning of the study[†]
- ▶ Explore changes in lactate dehydrogenase (LDH) from the beginning of the study[†]
- ▶ Explore changes in fatigue from the beginning of the study
- ▶ Measure the proportion of people who achieved normalization of Hb or LDH

C5i=C5 inhibitor; PNH=paroxysmal nocturnal hemoglobinuria.

[†]Noninferiority tests were used for these secondary goals. These tests determined if EMPAVELI was no worse than a C5i (eculizumab) compared from the beginning of the study.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about EMPAVELI? (cont'd)

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.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).

See how EMPAVELI was studied in PRINCE

The PRINCE clinical trial compared people taking EMPAVELI to people in a control arm, which meant they were not taking EMPAVELI or any type of complement inhibitor treatment. People in the control arm continued their non-complement inhibitor medications, if they were taking any.



53 adults with PNH were randomly divided into **2 groups** and studied for **26 weeks**

1st
group

received EMPAVELI
(n=35)

2nd
group

(the control arm)
continued their PNH treatment
without EMPAVELI or any other
complement inhibitor
(n=18)

These people had **never received complement inhibitor treatment** for their PNH before entering the trial. People entering the trial had an Hb level below normal.

Most people in the trial had been getting frequent blood transfusions to make up for low Hb levels. People entering the PRINCE trial had received an **average of 4 transfusions in the preceding year**.

Hb=hemoglobin; LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about EMPAVELI? (cont'd)

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.

Monica is an adult with PNH who's taken EMPAVELI.

Main goals of PRINCE

- ▶ Explore achieving stabilization of Hb levels
- ▶ Explore changes in LDH from the beginning of the study
- ▶ Safety: monitor the occurrence of side effects

Selected secondary goals and analyses

- ▶ See how many people could become transfusion-free
- ▶ Measure the proportion of people who achieved normalization of Hb
- ▶ Measure the proportion of people who achieved normalization of LDH

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

Increased hemoglobin with EMPAVELI

Superior improvements in hemoglobin (Hb) in people who had previously received a C5i: results at Week 16

Primary goal in the PEGASUS study: to explore whether EMPAVELI was better at improving Hb levels than a C5i (eculizumab) in people living with paroxysmal nocturnal hemoglobinuria (PNH)

In people who had previously received a C5i (PEGASUS)



People taking EMPAVELI had a
2.37 g/dL Hb INCREASE



People taking eculizumab had a
1.47 g/dL Hb DECREASE



**SUPERIOR
Hb DIFFERENCE**
of 3.84 g/dL with
EMPAVELI
compared to eculizumab
($P < 0.0001$)

IMPORTANT SAFETY INFORMATION (cont'd)

Who should NOT take EMPAVELI?

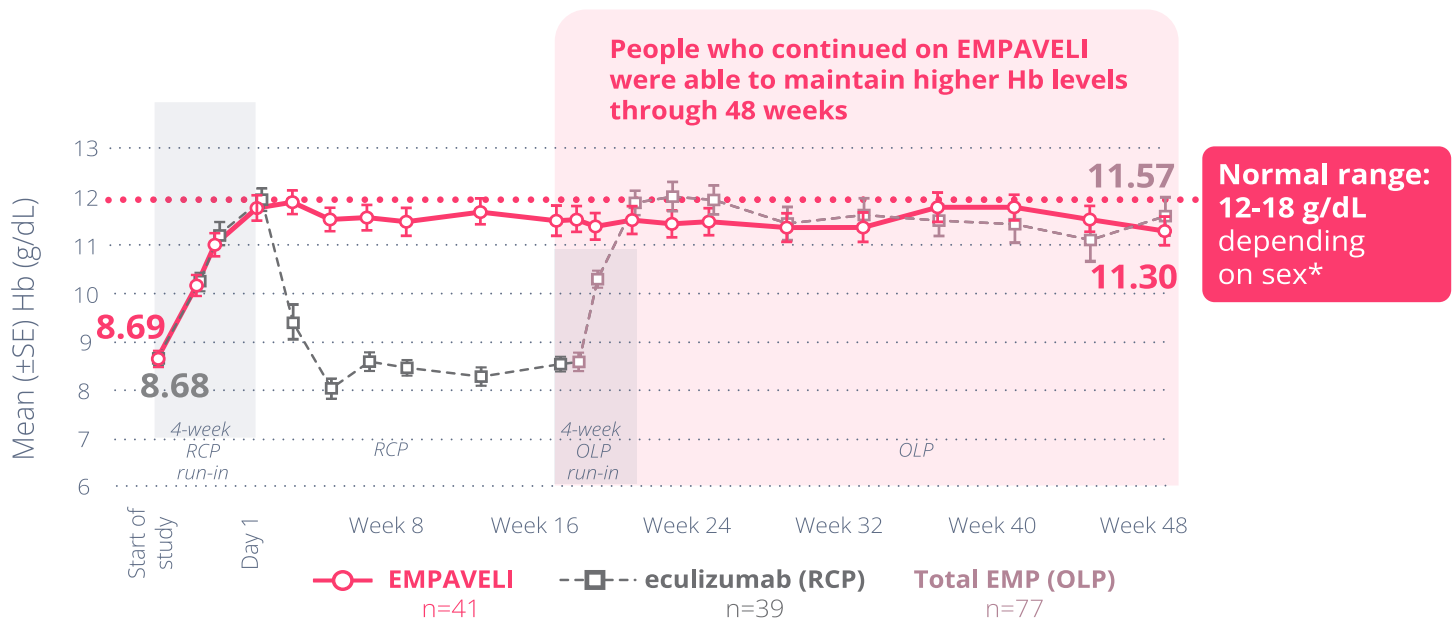
Do not take EMPAVELI if you:

- ▶ 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.

Peg is an adult with PNH who's taken EMPAVELI.

Hb improvement was maintained through the 48-week study

Average change in Hb levels from beginning to Week 48



*12-16 g/dL for females, 13.6-18 g/dL for males.

C5i=C5 inhibitor; EMP=EMPAVELI; OLP=open-label period; RCP=randomized control period; SE=standard error.

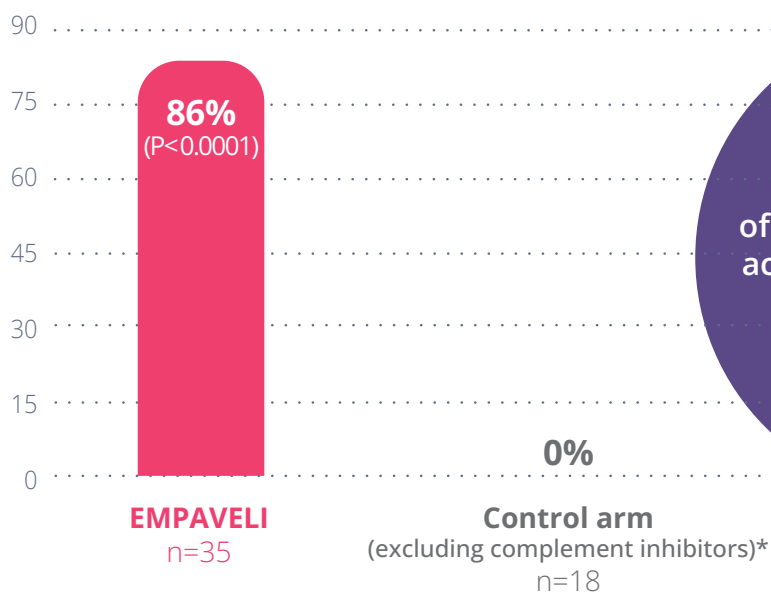
Please see additional Important Safety Information, including **Boxed WARNING** regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

Stabilized hemoglobin with EMPAVELI

Stabilized hemoglobin (Hb) levels in people who had never received a complement inhibitor: results at Week 26*

One of the primary goals in the PRINCE study: to explore whether EMPAVELI stabilized hemoglobin in people living with PNH not previously treated with a complement inhibitor

In people who had never received a complement inhibitor (PRINCE)



86%
of people taking EMPAVELI
achieved Hb stabilization
over 26 weeks

*Hb stabilization means avoiding a >1 g/dL decrease in Hb levels throughout the study.

PNH=paroxysmal nocturnal hemoglobinuria.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).

Stacey is an
adult with PNH
who's taken
EMPAVELI.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Avoiding the need for transfusions with EMPAVELI

Becoming transfusion-free with EMPAVELI vs eculizumab—in people who had previously received a C5i

At Week 16 in PEGASUS, EMPAVELI was no worse than a C5i (eculizumab) in helping people with PNH become transfusion-free.

In people who had previously received a C5i (PEGASUS)

85%
of people taking EMPAVELI
were **transfusion-free**



15%
of people taking a
C5i (eculizumab) were
transfusion-free

Becoming transfusion-free with EMPAVELI vs control arm—in people who had never received a complement inhibitor

At Week 26 in PRINCE, most people taking EMPAVELI were transfusion-free.

In people who had never received a complement inhibitor (PRINCE)

91%
of people taking EMPAVELI
were **transfusion-free**



6%
of people in the control arm
(excluding complement inhibitors)
were **transfusion-free**

IMPORTANT SAFETY INFORMATION (cont'd)

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.



"I have not needed a transfusion since I switched to EMPAVELI."

Individual experiences may vary.

”

Jillian is an adult with PNH who's taken EMPAVELI.

In people who had previously received a C5i (PEGASUS)

Reduced ARC

At Week 16 in PEGASUS, EMPAVELI was no worse than a C5i (eculizumab) in helping people with PNH reduce their ARC.

Average changes in ARC with EMPAVELI vs eculizumab—in people who had previously received a C5i

- ▶ People taking EMPAVELI saw their ARC **reduced by 136 x 10⁹ cells/L**
- ▶ People taking a C5i (eculizumab) saw an **increase in their ARC of 28 x 10⁹ cells/L**

ARC=absolute reticulocyte count; C5i=C5 inhibitor; PNH=paroxysmal nocturnal hemoglobinuria.

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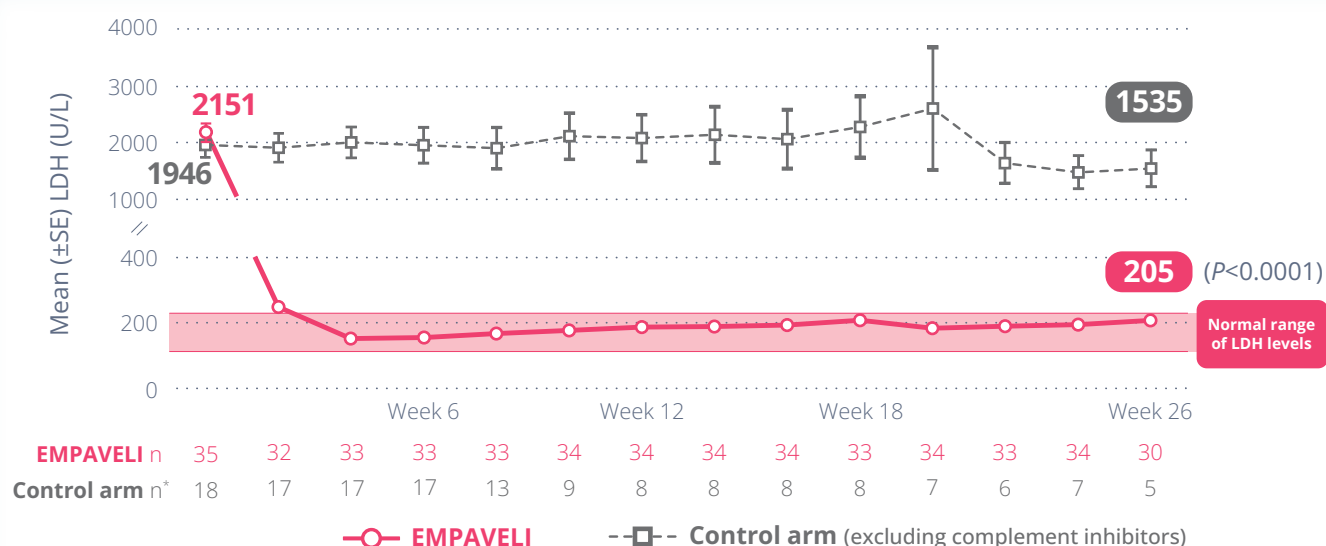
Changes in LDH with EMPAVELI

Rapid and sustained LDH reductions with EMPAVELI vs control arm—in people who had never received a complement inhibitor

One of the primary goals in the PRINCE study: to explore whether EMPAVELI reduced LDH in people living with PNH not previously treated with a complement inhibitor

By Week 2 in PRINCE, average LDH levels in the EMPAVELI group had dropped from baseline and remained there through 26 weeks.

In people who had never received a complement inhibitor (PRINCE)



At Week 26, average reductions in LDH levels were:

- ▶ -1870 U/L in the EMPAVELI group
- ▶ -400 U/L in the control arm (excluding complement inhibitors)

Changes in LDH levels with EMPAVELI vs eculizumab—in people who had previously received a C5i (PEGASUS)

At Week 16 in PEGASUS, it could not be determined if EMPAVELI was any worse than C5i (eculizumab) in reducing LDH.

C5i=C5 inhibitor; LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria; SE=standard error.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

Louis is an
adult with PNH
who's taken
EMPAVELI.

IMPORTANT SAFETY INFORMATION (cont'd)

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)

Changes in fatigue

Changes in fatigue with EMPAVELI vs eculizumab—in people who had previously received a C5i (PEGASUS)

Although it was not formally tested, people in the study were asked to report their changes in levels of fatigue at Week 16.

Measuring fatigue improvement

Fatigue was measured using the FACIT-Fatigue scale, a 13-question survey. In the survey, participants rated the level of impact they felt that their fatigue had on daily activities and function.

This information is for observation only and no conclusions can be made on the effect of EMPAVELI on fatigue. No comparisons can be made between those taking EMPAVELI and those taking eculizumab.



An increase of 5 or more points is seen as a clinically meaningful improvement.

IMPORTANT SAFETY INFORMATION (cont'd)

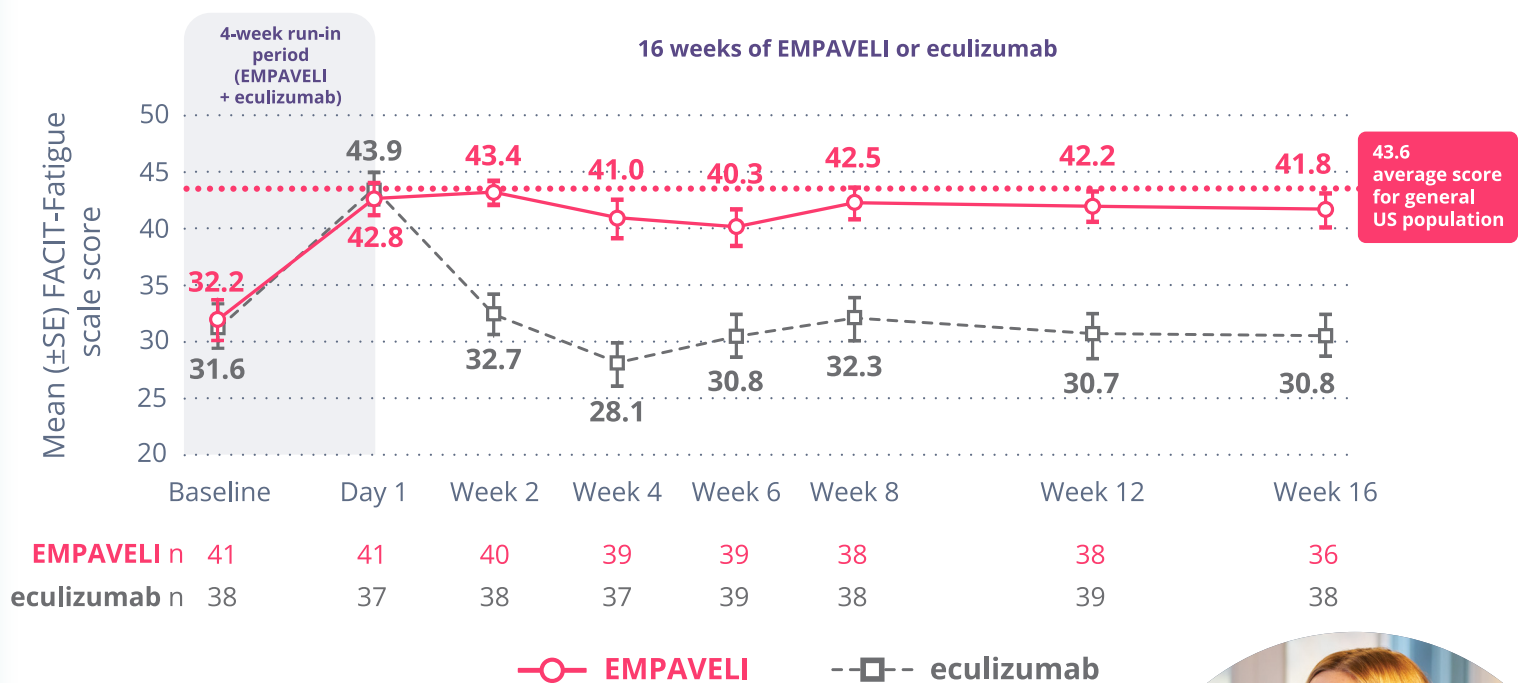
What are the possible side effects of EMPAVELI?

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
- ▶ wheezing
- ▶ swelling of 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

This information is for observation only and no conclusions can be made on the effect of EMPAVELI on fatigue. No comparisons can be made between those taking EMPAVELI and those taking eculizumab.

Average FACIT-Fatigue scores from beginning of study through Week 16



The FACIT-Fatigue scale ranges from 0 to 52.

Higher scores mean less fatigue.

These data include people who did and did not get a transfusion during the study.

Andrea is an adult with PNH who's taken EMPAVELI.

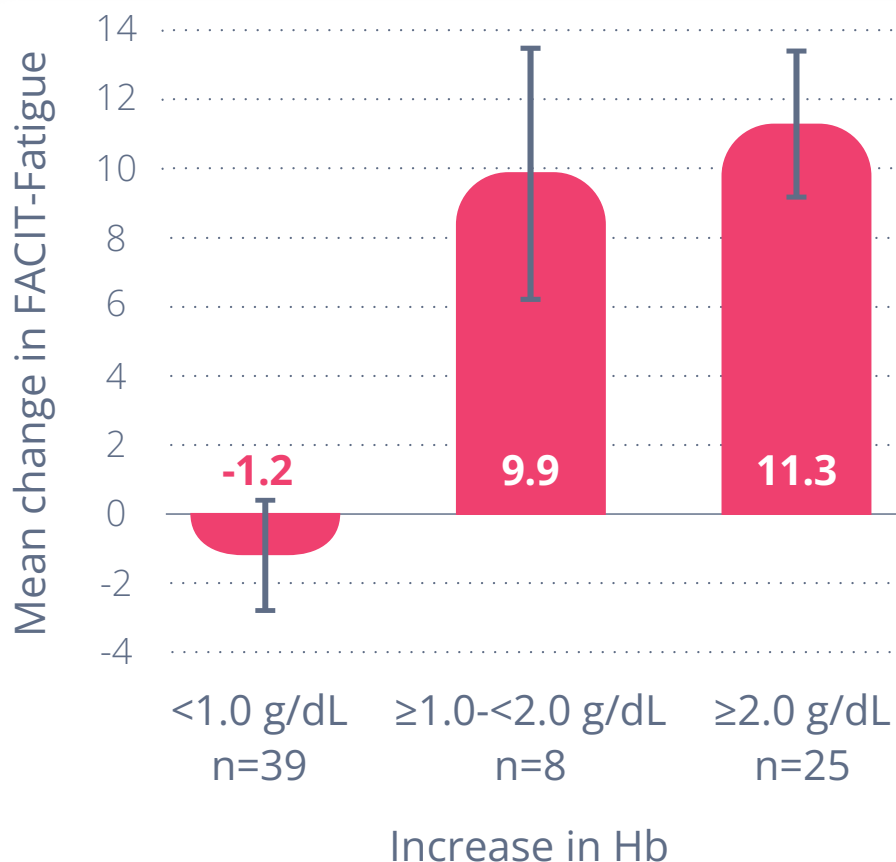


C5i=C5 inhibitor; FACIT=Functional Assessment of Chronic Illness Therapy; PNH=paroxysmal nocturnal hemoglobinuria; SE=standard error.

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A post hoc analysis of PEGASUS data found a link between Hb and fatigue

In people who had previously received a C5i (PEGASUS)



People with greater improvements in Hb showed larger reductions in fatigue

People with PNH who had an **Hb improvement of 1 g/dL or more** had an **average fatigue improvement of ~10 points**.

- ▶ A post hoc analysis gathers additional findings after a study has ended. It is not considered as scientifically strong as an analysis that was planned before the study began
- ▶ This analysis included people receiving EMPAVELI and people receiving eculizumab

C5i=C5 inhibitor; FACIT=Functional Assessment of Chronic Illness Therapy; Hb=hemoglobin; PNH=paroxysmal nocturnal hemoglobinuria.

Please see additional Important Safety Information, including **Boxed WARNING** regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

"I love leisurely walks and vacations with my family. With my increase in Hb levels and energy, I don't have to miss out."

Individual experiences may vary.

”

Andrea is an adult with PNH who's taken EMPAVELI.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of EMPAVELI? (cont'd)

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; pain in the arms, hands, legs, or feet; low potassium in blood; tiredness; viral infection; cough; joint pain; dizziness; headache; and rash.

Getting to normalization of lab values

What is normalization? How is it different than stabilization?

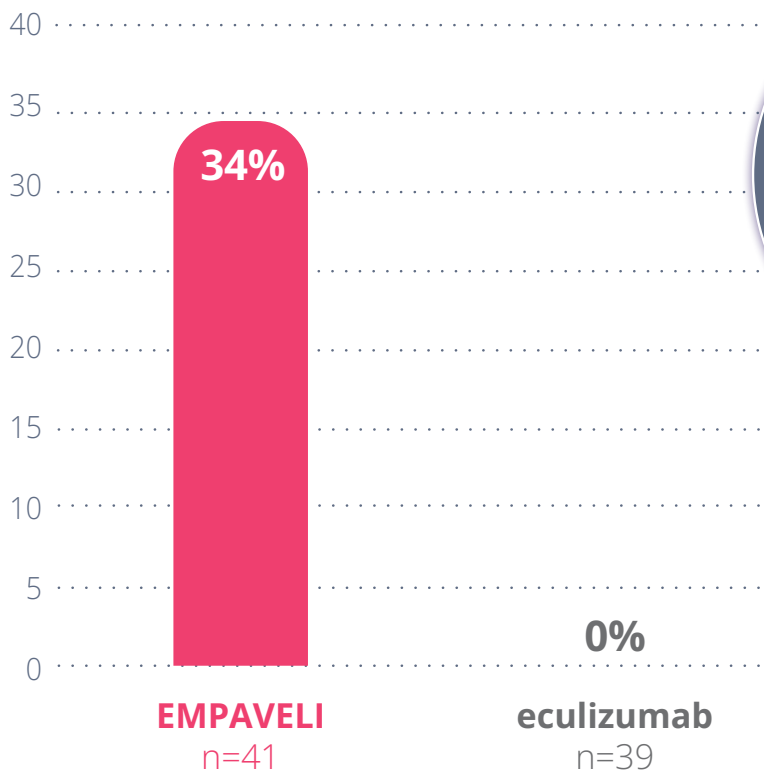
Normalization means lab values improved to levels like those of adults who don't have PNH. This is different than stabilization, which generally means that lab values did not get worse.

Hemoglobin (Hb) normalization in people with and without previous complement inhibitor treatment

This information is for observation only and no conclusions can be made on the effect of EMPAVELI on Hb normalization. No comparisons can be made between those taking EMPAVELI and those taking eculizumab in PEGASUS or those in the control arm (excluding complement inhibitors) in PRINCE.

In people who had previously received a C5i (PEGASUS)

At Week 16 in PEGASUS



34%

of people taking
EMPAVELI achieved
Hb normalization



Hb normalization means their Hb got to within the normal range (12-16 g/dL for females, 13.6-18 g/dL for males).

These data include only people who did not require a transfusion during the study.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of EMPAVELI? (cont'd)

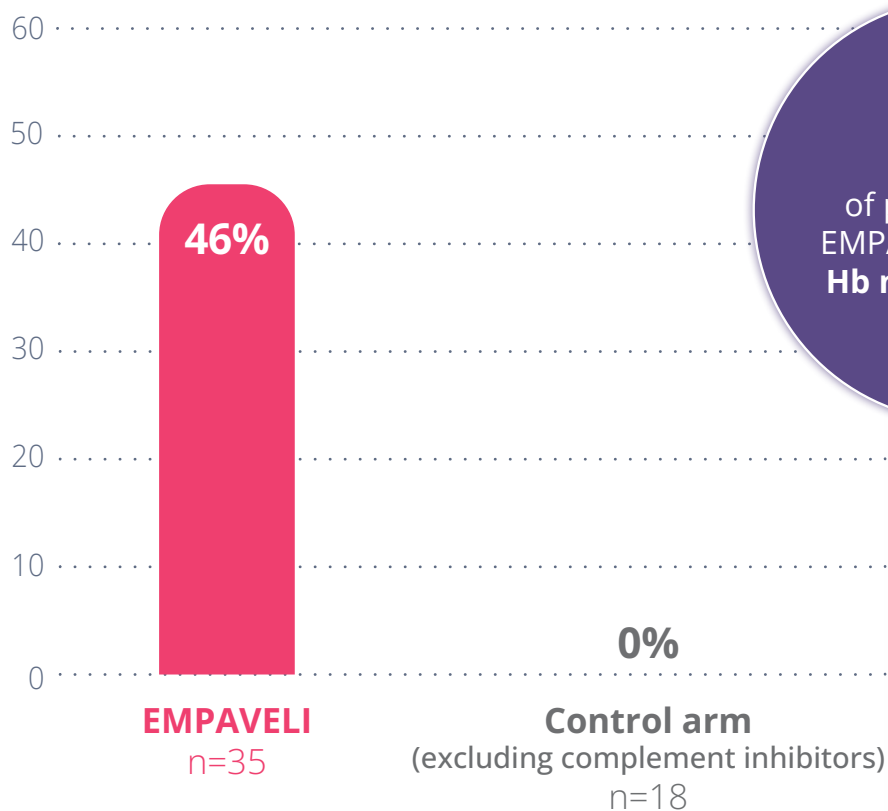
These are not all of the possible side effects of EMPAVELI. Tell your healthcare provider about any side effect that bothers you or that does not go away.

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.

Louis is an
adult with PNH
who's taken
EMPAVELI.

In people who had never received a complement
inhibitor (PRINCE)

At Week 26 in PRINCE



46%

of people taking
EMPAVELI achieved
Hb normalization



Hb normalization means
their Hb got to within the
normal range (12-16 g/dL
for females, 13.6-18 g/dL
for males).

These data include only people who did not require a transfusion during the study.

C5i=C5 inhibitor; PNH=paroxysmal nocturnal hemoglobinuria.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

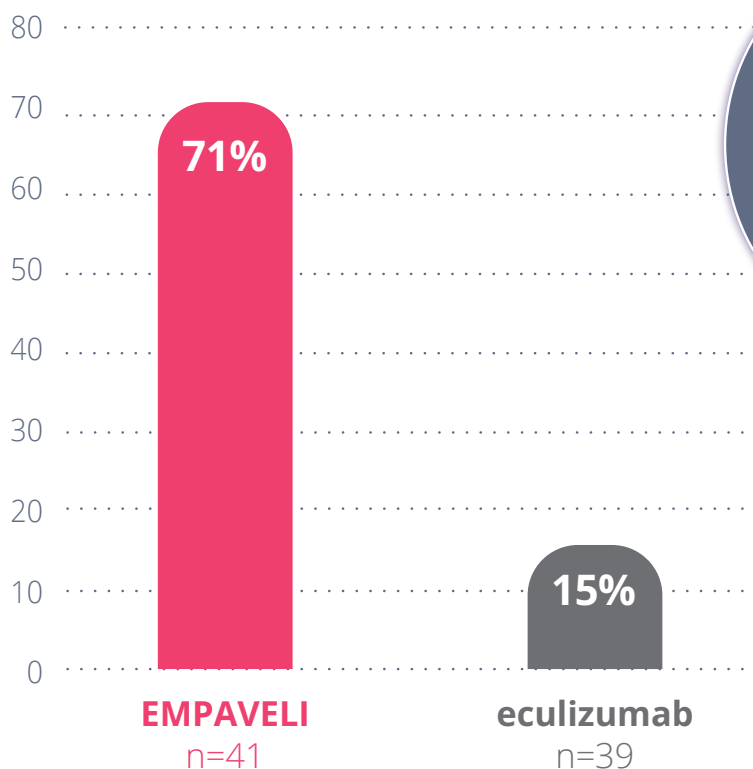
LDH normalization in people with and without previous complement inhibitor treatment

This information is for observation only and no conclusions can be made on the effect of EMPAVELI on LDH normalization. No comparisons can be made between those taking EMPAVELI and those taking eculizumab in PEGASUS or those in the control arm (excluding complement inhibitors) in PRINCE.

The majority of people taking EMPAVELI reduced their LDH levels to within the normal range (113-226 U/L).

In people who had previously received a C5i (PEGASUS)

At Week 16 in PEGASUS



These data include only people who did not require a transfusion during the study.

71%
of people taking
EMPAVELI achieved
LDH normalization



IMPORTANT SAFETY INFORMATION

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

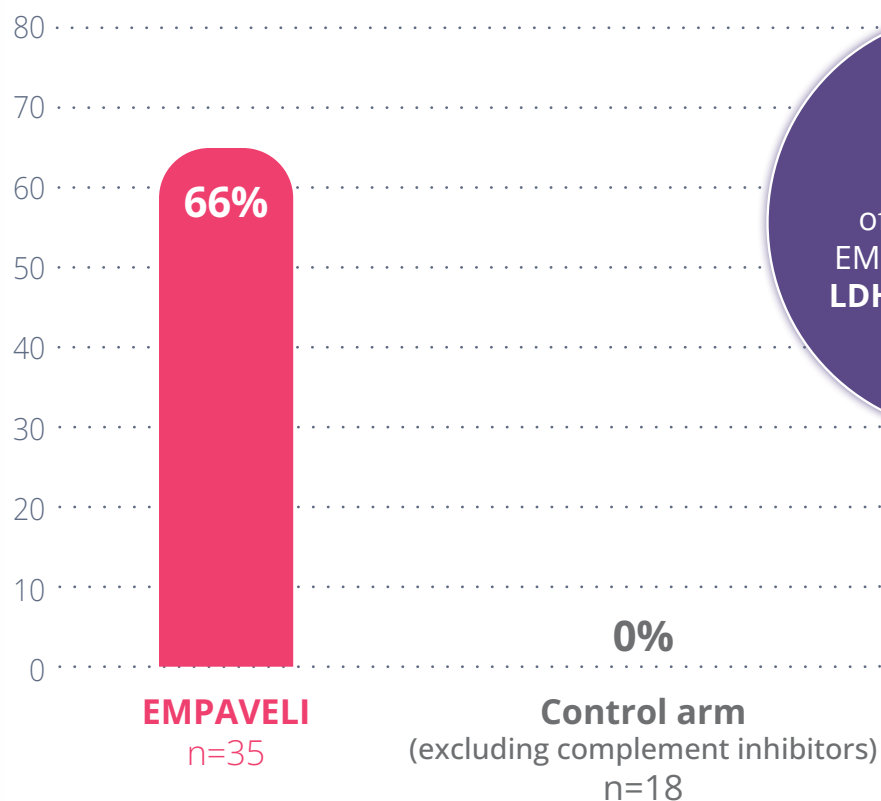
EMPAVELI is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

Nearly 2/3 of people taking EMPAVELI reduced their LDH levels to within the normal range (113-226 U/L).

Jillian is an adult with PNH who's taken EMPAVELI.

In people who had never received a complement inhibitor (PRINCE)

At Week 26 in PRINCE



66%
of people taking
EMPAVELI achieved
LDH normalization

These data include only people who did not require a transfusion during the study.

C5i=C5 inhibitor; Hb=hemoglobin; LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria.

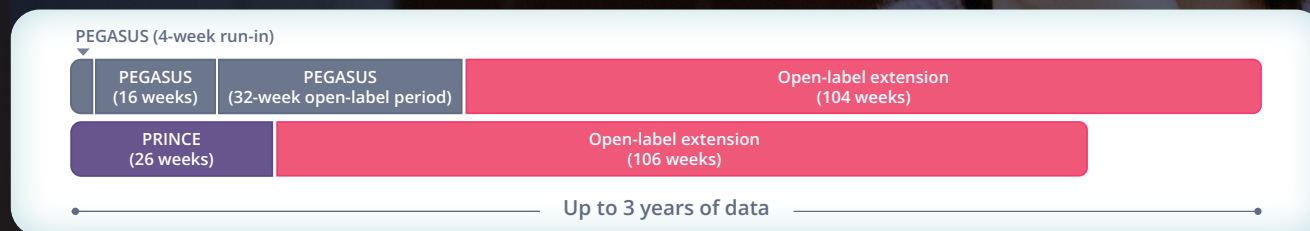
Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

Tori is an adult with PNH who's taken EMPAVELI.

Up to 3 years of results from an integrated analysis

An open-label extension study included adults with PNH (N=114) who enrolled and had previously completed the EMPAVELI Phase 3 studies (PEGASUS, PRINCE). Long-term data presented are from an integrated analysis of data in the subset of people who received 1080 mg of EMPAVELI by subcutaneous infusion twice weekly, or every 3 days, for up to 3 years (2.5 years, PRINCE; 3 years, PEGASUS).

An integrated analysis is an analysis of 2 or more sets of clinical trial data.



The goal of this analysis was to evaluate the long-term effectiveness and safety of EMPAVELI in treating adults with PNH.

Limitations:

- ▶ Data from this post hoc, integrated analysis are descriptive in nature, collected for observation only
- ▶ The analysis included a mixed group of people with PNH—those with previous C5i treatment (PEGASUS) and those without complement inhibitor treatment (PRINCE). Findings may not represent all people with PNH
- ▶ Baseline for those not originally assigned EMPAVELI in the trials was defined by when they started receiving EMPAVELI to evaluate the long-term effectiveness and safety of treatment with EMPAVELI

Most common side effects

- ▶ The most common adverse events ($\geq 10\%$) were infections and infestations (75.8%), injection site reactions (36.4%), abdominal pain (18.2%), fatigue (18.2%), headache (16.7%), and cough (12.1%)—consistent with those reported in the original studies

Serious side effects

- ▶ Two serious adverse events deemed related to EMPAVELI occurred: 1 case of biliary sepsis (severe infection of the gallbladder and associated structures) in PEGASUS and 1 case of sepsis (severe, potentially life-threatening infection throughout the body) in PRINCE

Overall, no new or unexpected side effects were identified.

C5i=C5 inhibitor; Hb=hemoglobin; LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria.

IMPORTANT SAFETY INFORMATION (cont'd)

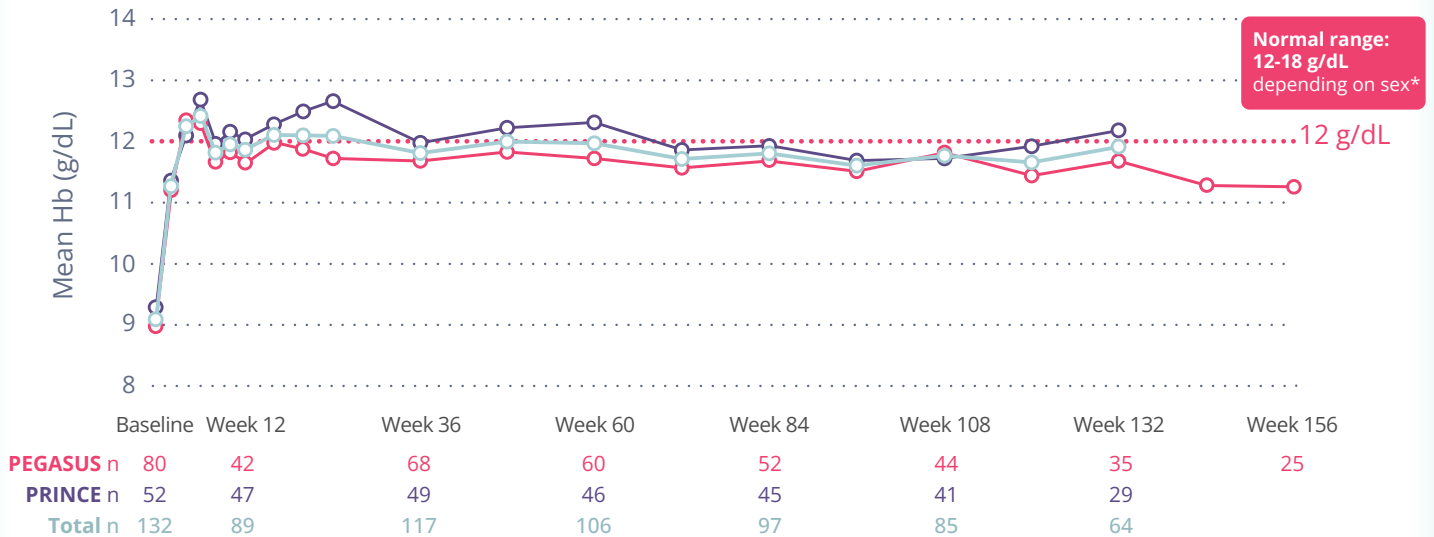
What is the most important information I should know about EMPAVELI? (cont'd)

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.

Long-term sustained Hb and LDH

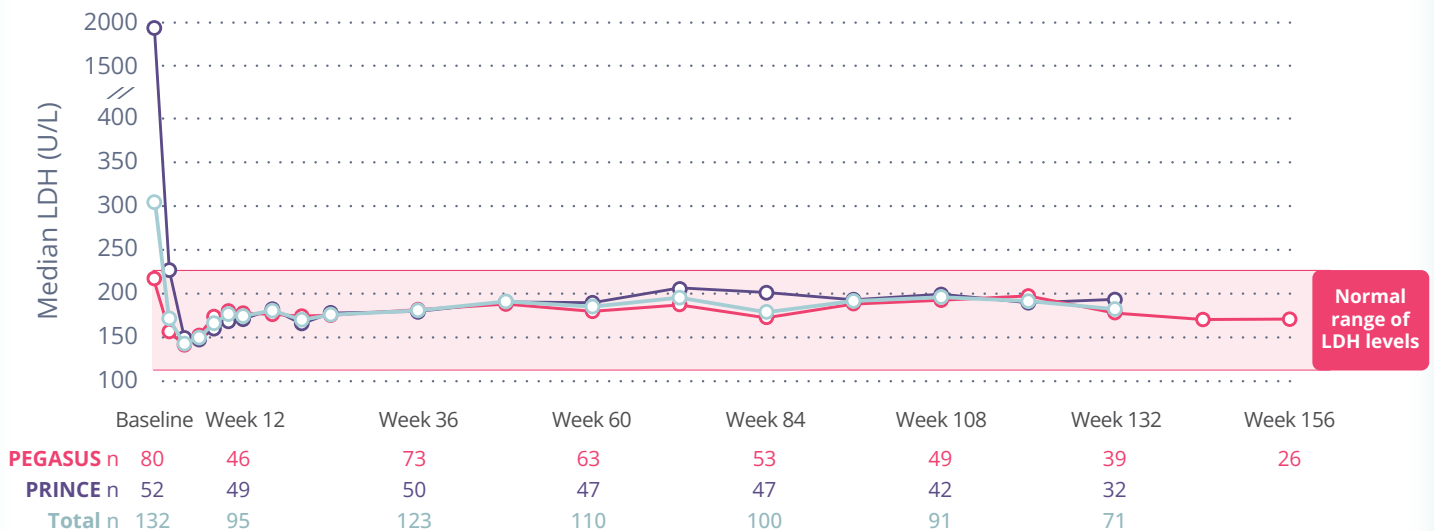
Hb levels up to 3 years



Patients who had a transfusion were not included in the Hb analysis for 60 days after the transfusion.

*12-16 g/dL for females, 13.6-18 g/dL for males.

LDH levels up to 3 years



Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

Most common side effects

PEGASUS
at Week 16

Injection site reactions



Infections



Diarrhea



Abdominal pain



Respiratory tract infection



Viral infection



Tiredness

► **Serious adverse reactions were reported in 17% of patients treated with EMPAVELI**

- The most common serious adverse events were infections (5%)
- Injection/infusion site reactions were mild or moderate in severity. Seventeen cases of diarrhea were reported during the 48 weeks. Fifteen of the cases were mild and 2 were moderate
- Breakthrough hemolysis occurred in 10% of those taking EMPAVELI vs 23% of those taking eculizumab at Week 16 in the PEGASUS study. Three people taking EMPAVELI left the study due to hemolysis

PRINCE
at Week 26

Injection site reactions



Infections



Viral infection



Pain in extremity



Low potassium



Joint pain



Dizziness



Abdominal pain



Rash



Headache

► **One patient treated with EMPAVELI died due to septic shock**

► **Serious adverse reactions were reported in 13% of patients treated with EMPAVELI**

- Overall, there were no EMPAVELI-related side effects leading to drug or trial discontinuation
- No events of acute hemolysis were observed in either treatment group through Week 26

► **These are not all the possible side effects of EMPAVELI. Be sure to tell your healthcare provider about any side effect that bothers you or that does not go away. Side effects can be reported to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**

- Two people taking EMPAVELI in the PEGASUS and PRINCE studies had side effects related to blood clots. They were deemed not related to EMPAVELI
- There have been no cases of encapsulated meningococcal infections in any adults with PNH treated with pegcetacoplan, as of 08/13/2024. They were vaccinated prior to treatment with pegcetacoplan

EMPAVELI REMS program ensures your safety is a top priority

EMPAVELI is only available through a program called the EMPAVELI REMS (Risk Evaluation and Mitigation Strategy).

REMS is a safety program run by the FDA. **Before you can take EMPAVELI, your healthcare provider must enroll in the program and will provide you with the following:**

- ▶ Counseling on the risk of serious infections caused by certain bacteria
- ▶ Information about the symptoms of serious infections
- ▶ Appropriate vaccinations against serious infections caused by encapsulated bacteria
 - You will receive antibiotics if you need to start EMPAVELI right away and are not up to date on your vaccines
- ▶ A Patient Safety Card
 - Carry this card with you at all times during treatment and for 2 months after your last EMPAVELI dose
 - Show this card to any healthcare professional to help diagnose and treat you quickly
 - Your risk of serious infection may continue for several weeks after your last dose of EMPAVELI

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [**Prescribing Information**](#) and [**Medication Guide**](#).

Self-administration with the EMPAVELI® Injector (pegcetacoplan)

EMPAVELI self-administration may fit into your lifestyle

EMPAVELI is a PNH treatment that you give yourself at home or wherever works for you (after receiving proper training).

EMPAVELI is self-administered subcutaneously (just under the skin). Self-administering EMPAVELI should take approximately 30 to 60 minutes.

- ✓ No intravenous (IV) infusions
- ✓ No infusion center visits
- ✓ No need to plan around infusion appointments

EMPAVELI can be self-administered using either:

- ▶ The EMPAVELI Injector; or
- ▶ A commercially available infusion pump with a reservoir of at least 20 mL

PNH=paroxysmal nocturnal hemoglobinuria.

IMPORTANT SAFETY INFORMATION (cont'd)

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



About the EMPAVELI Injector



- ▶ Push button starts injection and pops up when injection is complete
- ▶ The needle is never seen
- ▶ Compact device with no tubing involved
- ▶ The gauge shows the injection progress



You will be trained before using the EMPAVELI Injector for the first time. Refer to the EMPAVELI Injector Instructions for Use for more information.



"I love to travel. With EMPAVELI self-administration, I can bring my supplies with me and travel without interrupting my treatment schedule."

Emma is an adult with PNH who's taken EMPAVELI.
Individual experiences may vary.

When traveling, ensure that EMPAVELI stays at 36°F to 46°F (2°C-8°C).



Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

How do I take EMPAVELI?

EMPAVELI is self-administered just under the skin using a small, thin needle that you never see with the EMPAVELI Injector.

EMPAVELI is not an IV infusion (into the vein) that requires a healthcare provider to administer it for you.

How often do I take EMPAVELI?

- ▶ EMPAVELI is taken 2 times a week*
- ▶ The injection takes approximately 30 to 60 minutes

*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.



Scan the QR code to watch the EMPAVELI Injector self-administration video.

1080-mg dose
2x
WEEKLY*
For ~30-60 minutes



Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).



See the EMPAVELI Injector Instructions for Use or, if using an infusion pump, see those specific Instructions for Use.



Avoid intense physical activity and do not bump or knock the EMPAVELI Injector or button during the injection. Keep your stomach totally dry.



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



If your healthcare provider decides to stop your treatment with EMPAVELI, follow their instructions for how to stop. Your healthcare provider will monitor you closely for at least 8 weeks after stopping treatment with EMPAVELI for any signs of hemolysis due to PNH.



LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about EMPAVELI? (cont'd)

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

What else should I know before starting EMPAVELI?

You get self-administration support from the start

Your healthcare provider will first show you how to self-administer your EMPAVELI.

At Apellis, we understand each person's journey with PNH and EMPAVELI is different. With that in mind, we have designed our support services and self-administration training to fit comprehensive patient needs.

With the ApellisAssist patient support program, you will have the help of an Apellis Care Educator (ACE). ACEs have nursing backgrounds and will provide you with self-administration training. Your ACE can train you in your home or virtually—multiple times, if necessary—to make sure you're comfortable with the process.

They will continue to be by your side throughout your journey with ongoing support, education, and answers to your questions.

ACEs do not give medical advice. Talk to your doctor for treatment-related questions.



Mollie is
an Apellis
Care Educator.

There are processes for transitioning to EMPAVELI

Your healthcare provider will work with you to transition you to EMPAVELI.

Eculizumab

- ▶ For the first 4 weeks, you will receive EMPAVELI and your current dose of eculizumab
- ▶ After 4 weeks, STOP eculizumab and only take EMPAVELI

Ravulizumab

- ▶ You should start taking EMPAVELI no more than 4 weeks after your last dose of ravulizumab

Certain vaccines are required before starting EMPAVELI

Before starting your treatment journey with EMPAVELI, you will need to get certain vaccines. They help reduce the risk of certain serious infections.

You will be required to receive vaccinations against certain types of bacteria at least 2 weeks before taking your first dose of EMPAVELI.



As part of the ApellisAssist program, a Vaccine Coordinator through our specialty pharmacy, PANTHERx[®] Rare, can help you with this process.

Your Vaccine Coordinator can help make sure you get the required vaccines by:

- ▶ Researching local pharmacies based on your location and insurance coverage
- ▶ Creating a list of local options that have all required vaccines in stock along with information on hours of operations and how to make an appointment
- ▶ Contacting your pharmacy of choice to transfer any required prescription orders and make sure the pharmacy has all the appropriate information on file for billing the vaccines

When visiting your healthcare provider:

- ▶ Bring your vaccination records
- ▶ Ask your healthcare provider which vaccines you will need before starting EMPAVELI

Reach out to your healthcare provider if you have any additional questions about starting EMPAVELI.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about EMPAVELI? (cont'd)

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.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

Support every step of the way

The ApellisAssist program is here for you

It takes teamwork to help manage PNH. The ApellisAssist patient support program provides comprehensive support, with helpful resources and experienced people dedicated to making a difference for you.

With the program, you have access to:

- ▶ Financial assistance (for those who are eligible)
- ▶ Insurance support
- ▶ Self-administration training from an Apellis Care Educator (ACE)
- ▶ EMPAVELI and PNH education



1-866-MY-APL-ASSIST (1-866-692-7527)
FROM 8 AM-8 PM ET, MONDAY-FRIDAY

PNH=paroxysmal nocturnal hemoglobinuria.



Emma is an adult with PNH who's taken EMPAVELI.

”

“My ACE is amazing. Her training helped give me confidence in self-administering EMPAVELI. She continues to be there for me and is always a phone call away.”

Individual experiences may vary.

Your ApellisAssist support partners

With EMPAVELI, you don't have to go it alone.
Learn about your dedicated partners from the ApellisAssist program.



Care Coordinator

Through our specialty pharmacy, PANTHERx Rare, a Care Coordinator will:

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



Apellis Care Educator (ACE)

Your ACE is there for you from the start. They will provide you:

- ▶ 1-on-1 training on how to self-administer EMPAVELI—in your home or virtually
- ▶ Ongoing support every step of the way
- ▶ A wide variety of educational resources
- ▶ Answers to questions that may pop up

Care Coordinators and ACEs do not give medical advice. Talk to your doctor for treatment-related questions.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).

EMPAVELI

TRIAL OFFER

8 weeks of EMPAVELI treatment at no cost to eligible adults with PNH*

If you haven't tried EMPAVELI yet, you may be eligible for the EMPAVELI Trial Offer regardless of insurance coverage or current treatment.

- ✓ Straightforward enrollment for you and your healthcare provider
- ✓ The same comprehensive training and support as those currently taking EMPAVELI
- ✓ No obligation to continue with EMPAVELI after trial ends

If you and your healthcare provider are ready to try EMPAVELI, you may be eligible to enroll in the **Trial Offer program**.

*Terms, conditions, and eligibility requirements apply. Ask your doctor for more information.

Insurance questions? In need of financial assistance?

Call an ApellisAssist representative at **1-866-MY-APL-ASSIST (1-866-692-7527)** to connect with your Care Coordinator about insurance questions or financial assistance programs that are available for eligible patients.

Tools for your journey

Resources, tools, and tips designed for you

No matter where you are in your journey, there are many resources available to help.



A range of brochures and guides available to download



Extensive video content including patient stories, ACE support stories, and step-by-step instructions for taking EMPAVELI



Home Suite Home with tools and videos for traveling with, storing, and organizing your medication



Social communities to keep in touch on Facebook, Instagram, and YouTube

Angelo is an adult with PNH who's taken EMPAVELI.

Please see additional Important Safety Information, including **Boxed WARNING** regarding risk of serious infections, on pages 42-43, and accompanying full **Prescribing Information** and **Medication Guide**.

INDICATION 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).

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.
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.

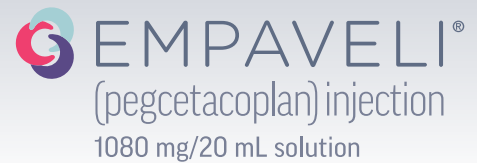
EMPAVELI is only available through a program called the EMPAVELI Risk Evaluation and Mitigation Strategy (REMS). Before you can take EMPAVELI, your healthcare provider must enroll in the EMPAVELI REMS program, counsel you about the risk of serious infections caused by certain bacteria, give you information 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.

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 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
- ▶ tiredness
- ▶ blood in your urine
- ▶ pain in the stomach (abdomen)
- ▶ shortness of breath
- ▶ blood clots
- ▶ trouble swallowing
- ▶ 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
- ▶ fast heart rate
- ▶ trouble breathing or shortness of breath
- ▶ nausea or vomiting
- ▶ wheezing
- ▶ feel confused or anxious
- ▶ swelling of 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 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.

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 additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).

Absolute reticulocyte count (ARC)

A test that measures the number of immature red blood cells in your blood. High reticulocyte counts may be a sign of ongoing hemolysis with paroxysmal nocturnal hemoglobinuria (PNH), as the body is making more new red blood cells to replace the ones being destroyed by the immune system.

C3

A protein in the blood that acts as a central point of the complement system, regulating its activation.

C5

Another protein in the blood that is part of the complement system.

Clinical trial

A type of research study that tests how well treatments work in people, as well as possible side effects of treatments.

Complement system

The complement system, also referred to as the complement cascade, is an army of more than 40 different proteins that work together to get rid of dangerous cells and fight infection.

Extravascular hemolysis (EVH)

Destruction of red blood cells that occurs in the liver or spleen.

FACIT-Fatigue scale

This tool consists of a number of questions that are used to assign a score to measure a person's experience with fatigue.

Globin'

Acting in pursuit of higher hemoglobin levels.

Hemoglobin (Hb)

The critical protein found inside red blood cells that enables other cells throughout the body to get the oxygen they need. Hemoglobin acts like drops of glue that can "stick" to oxygen and carry it from the lungs to other tissues. It can also "stick" to waste like carbon dioxide to help remove it from the body.

Hemolysis

The breaking apart of red blood cells. It can occur when the immune system attacks these cells as though they were dangerous viruses or bacteria. When red blood cells break open, hemoglobin is released. Hemolysis causes many of the symptoms of PNH.

Immune system

A sophisticated defense network used to protect the body from dangers like disease and infection.

Intravascular hemolysis (IVH)

The destruction of red blood cells inside a blood vessel.

Lactate dehydrogenase (LDH)

An enzyme found in the blood and tissues of the body, including the heart, kidneys, brain, and lungs. Red blood cell destruction results in the release of LDH into the blood. People with PNH often have higher levels of LDH due to ongoing hemolysis.

Normalization

Lab values improving to levels like those of adults who don't have PNH.

Proteins

Molecules that play many important roles in the body and can be thought of as the “workhorses” of cells. Proteins are required for the structure, function, and regulation of the body's organs and tissues.

Red blood cells

A common type of blood cell. Their job is to carry oxygen, using an important molecule, hemoglobin, around the body.

Stabilization

Lab values remaining at a stable level and not getting worse.

U/L

Some test results are reported in U/L, or units per liter. This is a measurement of how many units there are in a liter.

x 10⁹ cells/L

A short way to write a number with 9 zeros at the end. This is useful when needing to count the billions of cells in a liter of blood.

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).

If you're like Monica, an adult
with PNH taking EMPAVELI,

Where will you go next?



Scan the QR code
to learn more.

Explore the EMPAVELI Injector

Details and resources on using
the EMPAVELI Injector are available.



You don't have to go it alone

Your ApellisAssist team, including
your ACE, is always at your side.

ACE=Apellis Care Educator; PNH=paroxysmal nocturnal hemoglobinuria.

INDICATION 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).

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 additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 42-43, and accompanying full [Prescribing Information](#) and [Medication Guide](#).