

GETTING STARTED ON EMPAVELI

YOUR GUIDE TO TALKING WITH YOUR DOCTOR



Ready to start a conversation about the possibility of taking EMPAVELI, a treatment for adults and children 12 years of age and older with C3G or primary IC-MPGN that helps reduce protein in the urine (proteinuria)? Use this guide before, during, and after your appointments to take action, get answers, and find out if EMPAVELI is right for you.

Remember to print out this guide and bring it to your next appointment. You can fill it out on your computer or after printing.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is EMPAVELI[®] (pegcetacoplan)?

EMPAVELI is a prescription medicine used to treat adults and children 12 years of age and older with a kidney disease called complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce levels of protein in the urine (proteinuria).

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 Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 4-5, and the full [Prescribing Information](#) and [Medication Guide](#).



BEFORE YOUR VISIT

Tracking your symptoms and how you're feeling is important. It can help you and your doctor assess how C3G or primary IC-MPGN is impacting your daily life. Fill out this page before your visit to discuss with your doctor.

Your C3G or primary IC-MPGN treatment history

Currently, I'm taking: _____

In the past, I've taken: _____

How you're feeling

How do you feel C3G or primary IC-MPGN is affecting you?

I generally feel okay day to day I'm somewhat affected by my symptoms My symptoms really impact my daily life

Other: _____

Write down the symptoms you experience and, after printing this guide, fill in their severity.

	Mild	Moderate	Severe		Mild	Moderate	Severe				
_____	1	2	3	4	5	_____	1	2	3	4	5
_____	1	2	3	4	5	_____	1	2	3	4	5

What are my most recent labs?

You can keep track of your labs here—such as uPCR and eGFR, which help to monitor how your kidneys are doing—and may indicate whether treatment is working.

Lab/test name				
Date	Result	Result	Result	Result

Notes or additional questions: _____

C3G=C3 glomerulopathy; eGFR=estimated glomerular filtration rate; IC-MPGN=immune-complex membranoproliferative glomerulonephritis; uPCR=urine protein-to-creatinine ratio.



DURING YOUR VISIT

Here are some questions you and your doctor can answer and fill out together during your next appointment.

What do my most recent labs show about my disease? _____

How do my current treatment(s) help address my disease? _____

What are my current goals for treatment? _____



It can be hard to start a conversation about your goals or ask if starting treatment with EMPAVELI is right for you. Remember, you and your doctor are a team, and these questions can help you make a move against C3G or primary IC-MPGN to reduce proteinuria.

Tips for an empowered conversation with your doctor:



Plan your visit

Help keep the conversation focused with a list of topics or questions you want to discuss



Be open and honest

Being real about what you're thinking and how you're feeling may get you better answers



Use a support system

Have a friend or family member come with you if it'll help ease nerves or provide support



Get clarity

Ensure you leave with a full understanding of what was discussed and next steps

Talking about EMPAVELI

How could EMPAVELI help me reach my treatment goals? _____

How does EMPAVELI work? _____

How is EMPAVELI different from other treatments I've taken? _____

How is EMPAVELI administered and how often would I take it? _____

What if I need support to help me get started on EMPAVELI? _____

What are the potential risks and benefits of EMPAVELI? _____

How would EMPAVELI fit in with my routine? _____

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AFTER YOUR VISIT

You may have discussed a lot with your doctor during your appointment, but it's important to keep the conversation going so you can continue to be an active part of your treatment!



Keep track of your lab results and any changes in your condition



Stay in contact with your doctor, especially if you have any questions or concerns about your treatment



Connect with your support system when you need it

Ready to talk about EMPAVELI? Visit empaveli.com/c3g/stories to explore experiences of people like you.

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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

Please see additional Important Safety Information, including Boxed WARNING regarding risk of serious infections, on page 5, and the full [Prescribing Information](#) and [Medication Guide](#).

INDICATION AND 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.

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.

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 and can be life-threatening. Stop your EMPAVELI infusion and 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 your 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

The most common side effects in adults and children 12 years of age and older with C3G or primary IC-MPGN treated with EMPAVELI include injection-site reactions, fever, common cold, flu, cough, and nausea.

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.

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