

This guide can help you have a productive conversation with your doctor about your paroxysmal nocturnal hemoglobinuria (PNH) and **find a treatment option that's right for you**.



Approved Use What is FABHALTA?

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

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

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 7–9.

Important Safety Information

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

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

• FABHALTA 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 fatal if not recognized and treated early.

BEING PREPARED

Keeping track of how your PNH signs and symptoms are affecting you day to day and sharing those details with your doctor helps them understand how you're doing.

Whether you're newly diagnosed or have been living with PNH for some time, this guide can help you make the most of your doctor visits.

PNH can have a significant impact

The signs and symptoms of PNH may vary and can impact how you feel on a daily basis.



It can impact how you feel physically and emotionally



It can affect how you function day to day

Click one of the options below.



Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

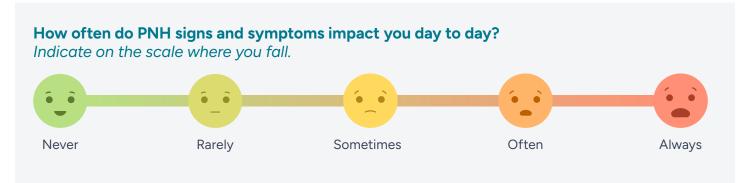
FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections. (continued)

- You must complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of FABHALTA.
- If you have not completed your vaccinations and FABHALTA therapy must be started right away, you should receive the required vaccinations as soon as possible.
- If you have not been vaccinated and FABHALTA must be started right away, you should also receive antibiotics to take for as long as your health care provider tells you.
- If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.



C5 INHIBITOR-TREATMENT EXPERIENCED

Take a moment to think about how you've been feeling lately. Then, fill out this page and bring it to your next appointment.



Do signs and symptoms of PNH impact how you feel on a daily basis? If so, in what way?

On a scale of 1-10, how do you feel about your current treatment?

1	2	3	4	5	6	7	8	9	10
Satisfied	<							\longrightarrow (Jnsatisfied

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections. (continued)

- Vaccines do not prevent all infections caused by encapsulated bacteria. Call your health care provider or get emergency medical care right away if you have any of these signs and symptoms of a serious infection:
 - Fever with or without shivers or chills
 Fever and a rash
 - Fever with chest pain and cough
 - Fever with high heart rate
 - Headache and fever
 - Confusion
 - Clammy skin

- - Fever with breathlessness or fast breathing
 - Headache with nausea or vomiting
 - Headache with stiff neck or stiff back
 - Body aches with flu-like symptoms
 - Eyes sensitive to light

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C5 INHIBITOR-TREATMENT EXPERIENCED

Starting a conversation about switching treatments isn't always easy, but it could help you discover other treatment options. It also may be an opportunity to reflect on your priorities or goals in the treatment process.

When it comes to PNH, I am concerned about: (Check all that apply)	My most recent Hb level is g/dL		
My need for red blood cell transfusions	I want my levels to:		
Infusion-based therapies	Improve Be normal		
My hemoglobin (Hb) levels Other:	Stay steady		
Other.			

Normal hemoglobin levels vary, but are generally between 12-16 g/dL for women and 13-18 g/dL for men.

If I could tell my doctor what I hope for, I would say:

Be sure to fill out a new copy of this page before every appointment. Then, look back at them to track changes to your symptoms over time.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections. (continued)

Your health care 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 weeks after your last dose of FABHALTA. Your risk of serious infections may continue for a few weeks after your last dose of FABHALTA. It is important to show this card to any health care provider who treats you. This will help them diagnose and treat you quickly.



JUST BEGINNING TREATMENT

Take a moment to think about how you've been feeling lately. Then, fill out this page and bring it to your next appointment. It may help you talk to your doctor about how you're doing and, together, you can determine your next steps.



Do signs and symptoms of PNH impact how you feel on a daily basis? If so, in what way?



Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is only available through a program called the FABHALTA Risk Evaluation and Mitigation Strategy (REMS). Before you can take FABHALTA, your health care provider must:

- Enroll in the FABHALTA 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 FABHALTA right away and you are not up to date on your vaccinations.
- Give you a Patient Safety Card about your risk of serious infections.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 7–9.



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JUST BEGINNING TREATMENT

Starting a conversation about PNH treatment isn't always easy, but it could help you learn more about your treatment options. It also may be an opportunity to reflect on what your priorities or goals are in the treatment process.

When it comes to PNH, I am
concerned about: (Check all that apply)

My need for red blood cell transfusions

Infusion-based therapies

My hemoglobin (Hb) levels

Other:

My most recent Hb level isg/dL							
I want my levels to:							
	Improve	Be normal					
	Stay steady						

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If I could tell my doctor what I hope for, I would say:

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Important Safety Information (continued)

Who should NOT take FABHALTA? Do not take FABHALTA if you:

- Are allergic to FABHALTA or any of the ingredients in FABHALTA.
- Have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae* type b when you are starting FABHALTA.



SUMMARY OF IMPORTANT INFORMATION FOR FABHALTA



What is FABHALTA?

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SUMMARY OF IMPORTANT INFORMATION



FOR FABHALTA (CONTINUED)

FABHALTA is only available through a program called the FABHALTA Risk Evaluation and Mitigation Strategy (REMS). Before you can take FABHALTA, your health care provider must:

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- Have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis,* or *Haemophilus influenzae* type b when you are starting FABHALTA.

Before you take FABHALTA, tell your health care provider about all your medical conditions, including if you:

- Have an infection or fever.
- Have liver problems.
- Are pregnant or plan to become pregnant. It is not known if FABHALTA will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if FABHALTA passes into your breast milk. You should not breastfeed during treatment and for 5 days after your final dose of FABHALTA.

Tell your health care provider about all the medicines you take, including prescription and overthe-counter medicines, vitamins, and herbal supplements. Taking FABHALTA with certain other medicines may affect the way FABHALTA works and may cause side effects.

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

If you have PNH and you stop taking FABHALTA, your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. Stopping treatment with FABHALTA may cause a breakdown of red blood cells due to PNH.

SUMMARY OF IMPORTANT INFORMATION



FOR FABHALTA (CONTINUED)

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

- Decreased hemoglobin level in your blood
- Shortness of breath
- Trouble swallowing
- Blood in your urine
- Tiredness
- Pain in the stomach (abdomen)
- Blood clots, stroke, and heart attack
- Erectile dysfunction (ED)

It is important you take FABHALTA exactly as your health care provider tells you to lower the possibility of breakdown of red blood cells due to PNH.

What are the possible side effects of FABHALTA?

FABHALTA may cause serious side effects, including:

- See "What is the most important information I should know about FABHALTA?"
- Increased cholesterol and triglyceride (lipid) levels in your blood. Your health care provider will do blood tests to check your cholesterol and triglycerides during treatment with FABHALTA. Your health care provider may start you on a medicine to lower your cholesterol if needed.

The most common side effects of FABHALTA in adults include:

• Headache

• Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)

- Pain in the stomach (abdomen)
- Infections (bacterial and viral)
- Nausea

• Diarrhea

Rash

Tell your health care provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of FABHALTA. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 7–9.

Please see full <u>Prescribing Information</u>, including Boxed WARNING and <u>Medication Guide.</u>

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