

WELCOME TO FABHALTA® (iptacopan)

This guide includes important vaccination information and helpful tips to navigate your treatment journey, so you can feel supported every step of the way.

C3G, complement 3 glomerulopathy; IgAN, immunoglobulin A nephropathy.

Approved Uses

What is FABHALTA?

FABHALTA is a prescription medicine used to:

- Treat adults with paroxysmal nocturnal hemoglobinuria (PNH).
- Reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly.

FABHALTA is approved based on a reduction of proteinuria. Continued approval may require results from an ongoing study to determine whether FABHALTA slows decline in kidney function.

- Treat adults with a kidney disease called complement 3 glomerulopathy (C3G), to reduce protein in the urine (proteinuria).

It is not known if FABHALTA is safe and effective in children with PNH, IgAN, or C3G.

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.

Please see additional Important Safety Information throughout and on pages 13-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

 **FABHALTA**
(iptacopan) 200 mg capsules

READY TO START FABHALTA?

Welcome to your FABHALTA journey.

We know that starting a different treatment can mean changes and a lot of new information.

Keep this brochure handy, and revisit it whenever you need as you get started with FABHALTA.

Use this guide to discover facts and tips about starting FABHALTA, including:



Navigating the insurance process



Getting ready to start FABHALTA



Starting FABHALTA



Patient portrayal.

Important Safety Information (continued)

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

- **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.
 - 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 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.

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Novartis Patient Support (NPS) can help you every step of the way with personalized assistance that can help you start, stay, and save on treatment.

With Novartis Patient Support, you have a dedicated team that can help you with:



Navigating the insurance process

Your dedicated Novartis Patient Support team will work with your provider to help navigate insurance coverage for your medication.



Financial support

Your dedicated Novartis Patient Support team will work with you to help identify financial support options. (See page 8 for more information about these options.)



Vaccination support

Our dedicated Novartis Patient Support team can help you locate vaccinations.



Ongoing support

Your dedicated Novartis Patient Support team is here for you with personalized support throughout your treatment and not just at the beginning.



Ready for personalized support through NPS? Click here ([C3G](#) or [IgAN](#)) or call 833-99FABHA (833-993-2242) to sign up.

Important Safety Information (continued)

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

- **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.
- 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 with chest pain and cough
 - Fever with high heart rate
 - Headache and fever
 - Confusion
 - Clammy skin
 - Fever and rash
 - 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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CO-PAY PLUS AND FABHALTA BRIDGE PROGRAM

\$0 Co-Pay Plus* offer

If you have private insurance, you may be eligible for the \$0 Co-Pay Plus* offer for FABHALTA through Novartis Patient Support.

FABHALTA Bridge Program[†]

If you have private or commercial insurance, FABHALTA Bridge Program[†] offers up to twelve (12) months of FABHALTA for free while we work with your health care provider and health insurance to help get your medication covered.



To enroll in Co-Pay Plus program, click [here](#) or call 833-99FABHA (833-993-2242).

***Co-Pay Plus:** Limitations apply. Patients with commercial insurance coverage for FABHALTA may receive up to \$20,000 in annual co-pay benefits for the cost of FABHALTA and up to \$1,000 for qualifying vaccination costs (excluding administrative fees). Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States, Puerto Rico and select territories. Void where prohibited by law. Additional restrictions may apply. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

†Bridge Program: Limitations apply. Patients with commercial insurance, a valid prescription for FABHALTA, and a denial of insurance coverage based on a prior authorization requirement may receive a monthly dose for up to 12 months or until insurance coverage approval, whichever occurs first. Not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state program, or where prohibited by law. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional restrictions may apply. Novartis reserves the right to rescind, revoke or amend this Program without notice.

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INSURANCE FAQs

Insurance coverage is a top-of-mind concern for many patients. As you prepare to get your first FABHALTA prescription, it could help to review this important information based on your individual insurance scenario.

“ The insurance FAQs are good because these are things I was wondering about, and I find it helpful and appreciate it because, to me, this shows that I won’t be alone in the insurance process. ”

– Real FABHALTA patient

What if I have private insurance and my coverage is delayed or denied?

If eligible, Co-Pay Plus can help you to:

- Get FABHALTA if your coverage is delayed. Co-Pay Plus can provide up to 12 months of FABHALTA for free* while seeking coverage. (Limitations apply. See terms and conditions on page 4.)
- Pay for your FABHALTA out-of-pocket costs once your coverage is approved. Out-of-pocket costs could be your co-pay, co-insurance, or deductible

***Bridge Program:** Limitations apply. Patients with commercial insurance, a valid prescription for FABHALTA, and a denial of insurance coverage based on a prior authorization requirement may receive a monthly dose for up to 12 months or until insurance coverage approval, whichever occurs first. Not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state program, or where prohibited by law. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional restrictions may apply. Novartis reserves the right to rescind, revoke or amend this Program without notice.

Important Safety Information (continued)

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

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(iptacopan) 200 mg capsules

INSURANCE FAQs (continued)

What if I have government insurance and my drug coverage is denied?

Insurance denial can be common and can be appealed. An appeal is a request for your insurance company to reconsider its decision about denying coverage of your medication. Your doctor will submit an appeal letter to your insurer, usually with your treatment records. You can also write a letter to go along with your doctor's appeal letter to explain why your claim should be accepted.

The **American Kidney Fund** offers general information about health insurance and patient rights. A few other organizations and support groups, such as **NephCure**, the **National Kidney Foundation**, and the **IgA Nephropathy Foundation**, may also be helpful. These organizations and their websites are independently operated and are not managed by Novartis Pharmaceuticals Corporation. Novartis assumes no responsibility for any information they may provide

Can I get access to my medication even if my insurance is denied?

Novartis Patient Assistance Foundation (NPAF), an independent nonprofit, provides Novartis medications free of cost to eligible patients who have limited or no prescription insurance coverage and cannot afford the cost of their medications. Learn more about eligibility and income requirements and enrollment at www.PAP.Novartis.com, or call NPAF at 1-800-277-2254.

If your coverage was denied, ask your care team about starting an appeal. Click here ([C3G](#) or [IgAN](#)) for more information on the appeals process.

Unfamiliar with the insurance process? Click here ([C3G](#) or [IgAN](#)) for a glossary of common insurance terms to keep yourself informed and up to date.

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 on pages 13-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.



WHY YOU NEED CERTAIN VACCINATIONS

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

The reason you need certain vaccinations before starting treatment is because 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.

You must complete or update the following vaccinations at least 2 weeks before your first dose of FABHALTA:

VACCINE	PURPOSE
Pneumococcal	Helps protect you from the risk of pneumonia caused by <i>Streptococcus pneumoniae</i> infection
Meningococcal	Helps protect you from the risk of meningitis caused by <i>Neisseria meningitidis</i> infection

Several types of pneumococcal and meningococcal vaccines are available. You may have received some of them in the past. Your health care provider will inform you of the vaccinations and number of doses you need based on your age and vaccination history.

Ask your doctor about any additional vaccinations that may be helpful.

Vaccines do not prevent all infections caused by encapsulated bacteria.

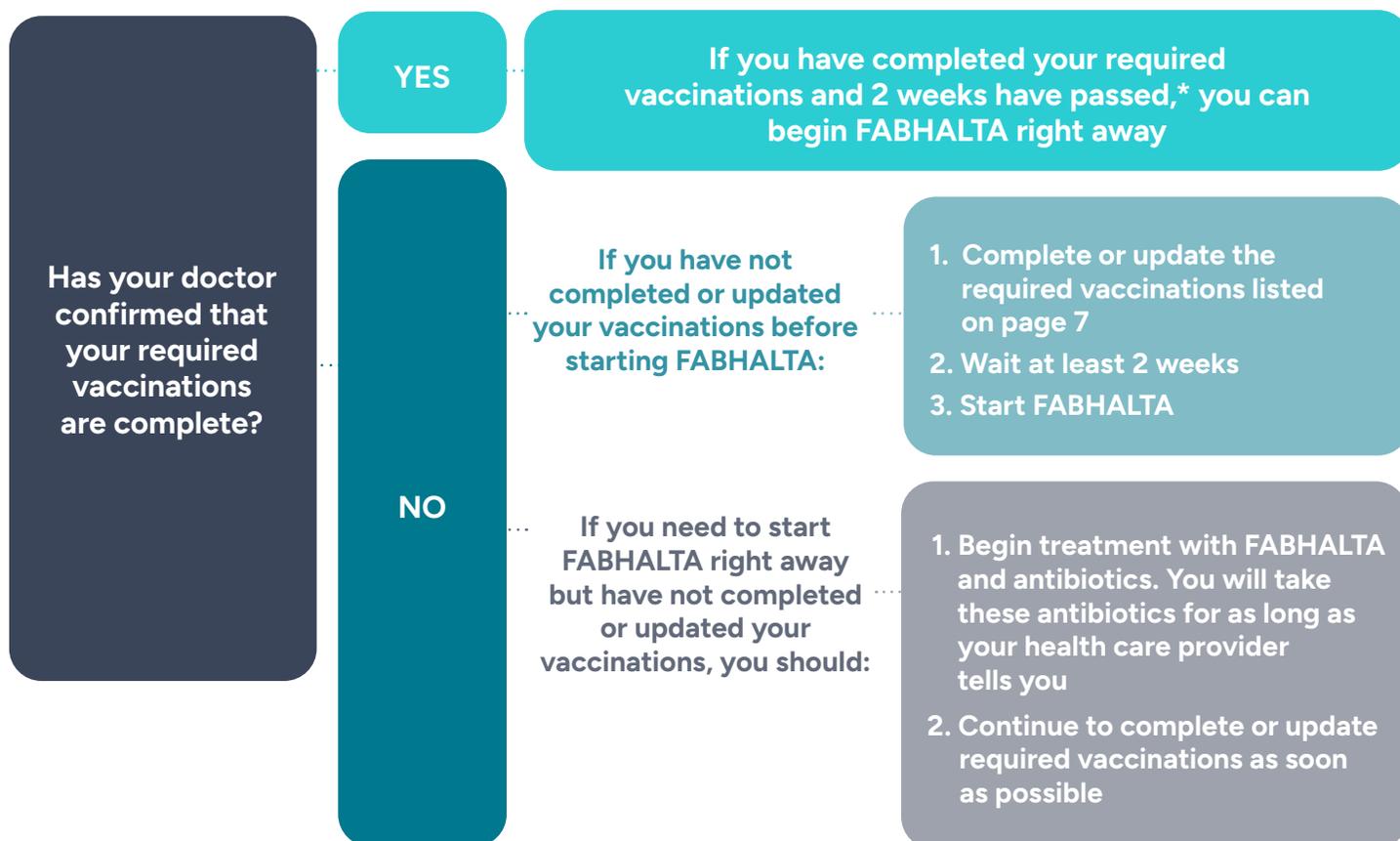
Call your health care provider or get emergency medical care right away if you have any of these signs and symptoms of a serious infection:

- Fever with or without shivers or chills
- Fever with chest pain and cough
- Fever with high heart rate
- Headache and fever
- Confusion
- Clammy skin
- Fever and rash
- 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

WHEN YOU NEED TO GET YOUR VACCINATIONS

Your health care provider will review your vaccination history and guide you through the dosing and scheduling options.

This chart can help you understand what is needed to start FABHALTA.



*While taking FABHALTA, you should be revaccinated according to current medical guidelines for encapsulated bacteria. Your health care provider or NPS can help you locate vaccinations.

Some vaccines may require more than 1 dose, so it's important to know how many doses you need for each.

THE FABHALTA REMS PROGRAM



Because of the risk of serious infection that comes with taking FABHALTA, it is only available through a restricted program called a 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

To learn more about the FABHALTA REMS program, please call the REMS helpline at 866-201-3101 between 8:00 AM and 4:00 PM ET or visit FABHALTA-REMS.com today.

The FABHALTA Patient Safety Card

Your health care provider will give you a Patient Safety Card about the risk of serious infections.

Carry this card 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.

If you notice any signs or symptoms described on this card, contact your doctor or get emergency medical assistance immediately.

HOW NPS AND YOUR CARE TEAM CAN HELP

NPS is here to help you begin your treatment with FABHALTA.

Our Vaccination Support program provides in-home vaccination and guided navigation to help simplify the vaccination process for eligible patients, regardless of insurance.

Vaccination Support consists of:



In-home vaccination—
a licensed clinician administering all required vaccinations in your home at no cost



Guidance throughout the vaccination process—helps you navigate the steps needed to receive the required vaccinations, including finding a vaccination location near you

We also offer guidance on accessing existing vaccination records.

Eligible patients can use their **Co-Pay Plus card*** to help lower their out-of-pocket costs to **as little as \$0** for the required vaccination(s), up to \$1,000 annually, excluding administration costs.



To sign up for NPS, simply visit support.fabhalta.com or call 833-99FABHA (833-993-2242).

***Limitations apply.** Up to a \$20,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at www.fabhalta.com for details.

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 **FABHALTA**
(iptacopan) 200 mg capsules

RECEIVING YOUR FABHALTA PRESCRIPTION

FABHALTA is only available through a specialty pharmacy.

Because FABHALTA is part of the REMS program, you must get it through a specialty pharmacy. A specialty pharmacy is a service that allows you to have your medication **shipped directly to your door** and refilled every month. Someone at the pharmacy will reach out to you directly with all the details, so check your messages and missed calls. You can also contact your doctor if you haven't heard anything or to get an update.

Some specialty pharmacies we work with include:

- CareMed (caredmedsp.com)
- Biologics by McKesson (biologics.mckesson.com)



Step 1: You'll get a 30-day supply each month



Step 2: Five to 10 days before you run out, your specialty pharmacy should call you to schedule your refill

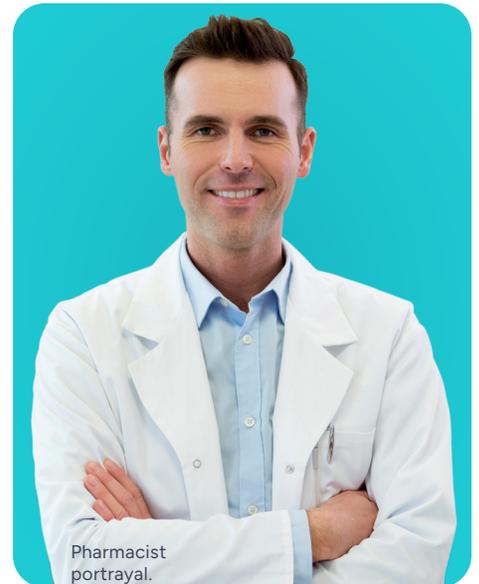


Step 3: Keep an eye on the number of capsules you have left

- If you are running low on your medication and haven't heard from your specialty pharmacy, call them ASAP



Save the number so you won't miss any future calls



Pharmacist portrayal.

If you have any remaining questions, visit [our website](#) to learn more about getting started on FABHALTA (C3G or IgAN).

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.

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Starting FABHALTA

ONE CAPSULE. TWICE A DAY.



Fit FABHALTA into your routine

- Each capsule contains 200 mg of FABHALTA
- Take 1 capsule twice a day with or without food
- Swallow the capsules whole
- **Do not** open, break, or chew capsules



What to do if you miss a dose or doses

If a dose or doses are missed, take 1 dose of FABHALTA as soon as you remember, even if it is almost time to take your next scheduled dose, and then take your next dose at your regularly scheduled time.

Take FABHALTA exactly as your doctor tells you. Do not change the dose or stop taking FABHALTA unless your doctor tells you.

Form a daily routine to help you remember to take FABHALTA twice a day.

Try incorporating your doses into activities you do every morning and evening, such as:

- Brushing your teeth in the morning and at night
- Eating breakfast and dinner
- Waking up and going to bed
- Getting dressed in the morning and getting changed at night
- Taking pets for a walk or feeding them

Use tools to help you set up reminders:

- Signing up for a dose or medication reminder program or app
- Using your smartphone to set alarms
- Setting up daily reminders on a digital calendar
- Placing a pillbox or travel pill organizer in an obvious, easy-to-remember place

[Click here \(C3G or IgAN\) for more on FABHALTA dosing and tips for incorporating it into your daily routine.](#)

Important Safety Information (continued)

Who should NOT take FABHALTA? (continued)

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.

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 **FABHALTA**[®]
(iptacopan) 200 mg capsules

APPROVED USE AND IMPORTANT SAFETY INFORMATION FOR FABHALTA (iptacopan)

Approved Uses

What is FABHALTA?

FABHALTA is a prescription medicine used to:

- Treat adults with paroxysmal nocturnal hemoglobinuria (PNH).
- Reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly.

FABHALTA is approved based on a reduction of proteinuria. Continued approval may require results from an ongoing study to determine whether FABHALTA slows decline in kidney function.

- Treat adults with a kidney disease called complement 3 glomerulopathy (C3G), to reduce protein in the urine (proteinuria).

It is not known if FABHALTA is safe and effective in children with PNH, IgAN, or C3G.

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.
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 - If you have not completed your vaccinations and FABHALTA 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.

- 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 with chest pain and cough
- Fever with high heart rate
- Headache and fever
- Confusion
- Clammy skin
- Fever and rash
- Fever with breathlessness or fast breathing
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- Headache with stiff neck or stiff back
- Body aches with flu-like symptoms
- Eyes sensitive to light

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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 over-the-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.

For people with PNH:

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

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

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

- 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)
- Diarrhea
- Pain in the stomach (abdomen)
- Infections (bacterial and viral)
- Nausea
- 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 www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and on page 13, and full Prescribing Information, including Boxed WARNING and Medication Guide.



READY TO GET STARTED

After reading through this brochure, we hope you feel prepared to begin your journey with FABHALTA. If you would like more support or more detailed information on other FABHALTA-related topics, check out these helpful resources:

Staying Up-to-Date on IgAN and Explore Resources



Sign up to receive emails on FABHALTA-related topics at FABHALTA.com/IgAN/sign-up

Staying Up-to-Date on C3G and Explore Resources



Sign up to receive emails on FABHALTA-related topics at FABHALTA.com/C3g/sign-up



Want to share your FABHALTA story?

Help inspire and empower others with IgAN or C3G by sharing your experiences.

Call 877-879-0245 (8 AM to 5 PM PT) or email info@voices-of-inspiration.com

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