



See what you can do before, during, and after your appointments with your care team and determine if FABHALTA is the right option for you.



#### **Approved Use**

What is FABHALTA?

FABHALTA is a prescription medicine used to 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 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.

### BEFORE YOUR APPOINTMENT

Your appointment will give you a chance to speak with your doctor about treatment options, so now is the best time to prepare for that visit to discuss an FDA-approved oral treatment option for adults with C3G.

Think about how you're currently feeling. It's critical to communicate the continued impact of living with C3G. This helps your doctor understand your unique journey and you can ask him whether FABHALTA, the first and only FDA-approved oral treatment in adults with C3G, to reduce proteinuria, may be right for you.

How are you t	feeling?	Check all the boxes that are true for you.

I'm doing everything I can, but I'm not satisfied with my current care plan

I struggle to cope with my C3G

I'm worried that my proteinuria is not improving

Use this space to write down how	you're feeling
so you can remember the details v	vhen you speak
to your care team:	

#### Notice any symptoms?

Tracking your symptoms may help you reflect on how you're doing. Think about the symptoms you've been experiencing and write them down here.

Rate their severity using the scale to the right.

 Mild 1		Moderate 3	_4_	Severe 5
 1)—			_4_	
<u>(1)</u> —	(2)	(3)	<b>—(4)</b> —	(5)

#### **Check your lab numbers**

As you may know, proteinuria refers to high levels of protein in the urine. Proteinuria levels are one of many indicators that can help both you and your doctor understand how your kidneys are doing. If you have elevated levels of proteinuria, talk to your doctor about taking a different approach to treatment.

Here, you can write in your most recent proteinuria results. Proteinuria is measured using the urine protein-to-creatinine ratio (UPCR) test:

Date	g/g	Date	g/g	Date	g	g/g

#### **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.



### **DURING YOUR APPOINTMENT**

Taking notes during your appointment can be helpful later on. You may want to bring along a family member or friend to take on this role. Ask questions when you don't understand something. This way, you and your doctor can have a shared understanding on how you're doing and whether your treatment is working.

#### Set your treatment goals

Before you and your doctor settle on a path forward, be sure to discuss your treatment goals and options.  These are objectives you hope to achieve through treatment. Write them down here so you can track your progress as you go.				
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#### Take an active approach

Here are 6 tips to help you maximize your conversations with your doctor:

- 1 Create an agenda: Create a list of topics you want to cover and introduce them when your appointment begins.
- **Be honest:** Providing detailed information to your doctor may help give them a better picture of your experience.
- 3 Ask questions: It's okay to ask as many questions as you need to understand what your doctor is saying.
- 4 **Bring someone:** A family member or friend might help you feel more comfortable or even ask questions you might not think of.

- 6 Be a team: By setting clear goals and keeping consistent communication with your care team, you can feel confident in your treatment plan going forward.
- 6 Set realistic goals: Adapting your lifestyle to C3G can be hard. Being open with your doctor about your struggles can help. You and your care team can work together to come up with and maintain realistic changes that help you manage your C3G.

#### **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.
  - 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.



## DURING YOUR APPOINTMENT (CONTINUED)

#### Ask about FABHALTA®

FABHALTA is the first and only FDA-approved oral treatment for adults with C3G, to reduce proteinuria.



FABHALTA is a prescription medicine used to reduce proteinuria in adults with C3G. It is not known if FABHALTA is safe and effective in children with C3G.

#### Here are some questions to ask your doctor about FABHALTA:

• How is FABHALTA different from other medications I may have taken before?

You can use this space to write additional questions or answers from your doctor

- Is there support available to help me get started on FABHALTA?
- Is FABHALTA an option for me?
- How can FABHALTA help reduce my proteinuria levels?
- Does FABHALTA fit my treatment goals?

Tou can use this sp	ace to write addit	ional questions of	diswers from y	our doctor.	

Learn more about how FABHALTA works at www.FABHALTA.com/C3G.

#### **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.
  - 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.



## AFTER YOUR APPOINTMENT

It's important to stay on top of your disease and treatment. Here are some things to consider doing after your appointment:



#### **Get ready to start FABHALTA**

Ask your doctor about what vaccinations you will need, Novartis Patient Support, and more! For more on getting started, see our <u>Patient Onboarding Brochure</u>.



#### **Stay proactive**

Don't wait for your next appointment to ask your doctor about FABHALTA. If you have updates, questions, or concerns, be sure to reach out to your care team right away.



#### **Monitor your condition**

If you notice anything new with your disease or have any problems with your medications, let your doctor know immediately.



#### Tap into your support system

Leaning on your family and friends may help you stay on top of your disease and medications, as well as find comfort through any ups and downs. For more resources to help a caregiver do their job, see our <u>Caregiver Brochure</u>.



Patient portrayal.

FABHALTA is the first and only available FDA-approved oral treatment option for adults with a kidney disease called complement 3 glomerulopathy (C3G), to reduce protein in the urine (proteinuria). Please refer to the <u>Onboarding Brochure</u> and <u>Caregiver Brochure</u> throughout your journey to refresh your memory or learn more.

#### **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



## APPROVED USE AND IMPORTANT SAFETY INFORMATION FOR FABHALTA (iptacopan)

#### **Approved Use**

#### What is FABHALTA?

FABHALTA is a prescription medicine used to 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 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.
  - 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.

- 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

## 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 guickly.

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.

Important Safety Information continues >>



# APPROVED USE AND IMPORTANT SAFETY INFORMATION FOR FABHALTA (iptacopan)

(CONTINUED)

- 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.

#### 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.

## 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.

#### 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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call <a href="https://www.fda.gov/medwatch">1-800-FDA-1088</a>.



