

# WELCOME TO FABHALTA<sup>®</sup> (iptacopan)

This guide can help you navigate your journey with FABHALTA,  
and feel supported every step of the way

IgAN, immunoglobulin A nephropathy.

## Approved Use

### What is FABHALTA?

FABHALTA is a prescription medicine used to reduce protein in the urine (proteinuria) in adults with primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly. It is not known if FABHALTA is safe and effective in children with IgAN.

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.

## 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 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).



**FABHALTA<sup>®</sup>**  
(iptacopan) 200 mg capsules

# PREPARING TO START FABHALTA

## Welcome to the start of your FABHALTA journey.

We know that starting a different treatment can mean changes and a lot of new information. This brochure can help walk you through your treatment journey with FABHALTA.

Different parts of this brochure may be relevant to you at different points down the road, so keep this handy as you get started and throughout your treatment.

### Use this checklist to help you prepare to get started on FABHALTA:

- See how Novartis Patient Support can help ([See page 3](#))
- Complete or update your vaccinations ([See page 4](#))
- Speak to your doctor about whether you need antibiotics ([See page 4](#))
- Understand the Risk Evaluation and Mitigation Strategy (REMS) program ([See page 5](#))
- Work with your specialty pharmacy ([See page 6](#))
- Fit FABHALTA into your daily routine ([See page 7](#))
- Check your insurance coverage for FABHALTA ([See page 8](#))
- Access Co-Pay and financial support if eligible ([See page 10](#))
- Find FABHALTA resources ([See page 14](#))

### 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.

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full Prescribing Information, including **Boxed WARNING** and Medication Guide.

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules



Patient portrayal.

Novartis Patient Support 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.



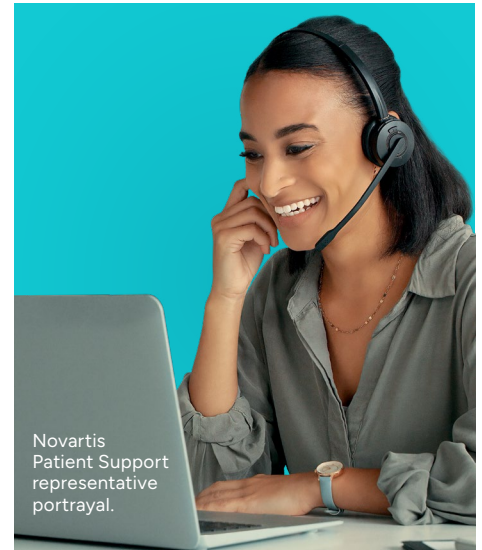
### **Vaccination support**

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. Not just at the beginning.



Novartis Patient Support representative portrayal.



**Ready for personalized support through Novartis Patient Support? Scan the QR code, click [here](#), or call [1-833-99FABHA \(1-833-993-2242\)](#) 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.
  - 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.

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).



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

# COMPLETE REQUIRED VACCINATIONS BEFORE STARTING FABHALTA

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

**FABHALTA affects part of your immune system and may lower your ability to fight infections. You must complete or update required vaccinations before starting FABHALTA and your care team will be there to help along the way.**

FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria, including *Streptococcus pneumoniae* (pneumonia), *Neisseria meningitidis* (meningitis), 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 starting FABHALTA

### If FABHALTA needs to be started right away, but



- **You haven't been vaccinated:** You should also receive antibiotics to take for as long as your doctor tells you
- **You haven't completed\* your vaccinations:** You should receive the required vaccinations as soon as possible

**If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your doctor will decide if you need additional vaccinations.**

While taking FABHALTA, you should be revaccinated according to current medical guidelines for encapsulated bacteria.

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

The most common adverse reactions in adults with IgAN ( $\geq 5\%$ ) with FABHALTA were upper respiratory tract infection (nasal congestion, runny nose, cough, sneezing, and sore throat), lipid disorder, and abdominal pain (stomach pain; includes abdominal discomfort, abdominal pain, upper abdominal pain, and gastrointestinal pain).

**Tell your health care provider about any side effect that bothers you or that does not go away. These are not all of 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

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 a 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

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# 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

## **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.**

To learn more about the FABHALTA REMS program, please call the REMS helpline at [1-866-201-3101](tel:1-866-201-3101) between 8:00 AM and 4:00 PM ET or visit [FABHALTA-REMS.com](http://FABHALTA-REMS.com) today. To learn more, review the [Medication Guide](#).

## **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 a 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

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including **Boxed WARNING** and [Medication Guide](#).



**FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# RECEIVING YOUR FABHALTA PRESCRIPTION

## FABHALTA is available only 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 HCP if you haven't heard anything or to get an update.

Some specialty pharmacies we work with include:

- CareMed ([caremedsp.com](http://caremedsp.com))
- Biologics by McKesson ([biologics.mckesson.com](http://biologics.mckesson.com))



**You'll get a 30-day supply each month**



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



**Save their number so you won't miss any future calls**



**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



## 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.

**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 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).



**FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# FIT FABHALTA INTO YOUR ROUTINE



## One capsule. Twice a day.

- Each capsule contains 200 mg of FABHALTA
- Take one 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 one 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 obvious, easy-to-remember places

## 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.

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# 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.**

## What if I have private insurance?

We are here to help you as you work with your insurance provider to get your medication approved for coverage. You shouldn't have to worry about delays in your treatment while waiting for your private insurance to cover you. In some cases, Novartis Patient Support can provide access to your medication for free while working with your doctors and health plan to get coverage.\* Sometimes this support may be included as part of Co-Pay Plus.† Your dedicated Novartis Patient Support team will work with you to help identify financial support options.

## What if my prescription isn't covered?

If your prescription isn't covered by your insurance provider, Novartis Patient Support can help by connecting you with Novartis Patient Assistance Foundation (NPAF). They'll tell you about eligibility, income, and out-of-pocket criteria that may vary by product. For additional information, please visit [www.PAP.Novartis.com](http://www.PAP.Novartis.com). To check eligibility and enroll in NPAF, please ask your doctor to submit a Start Form to Novartis Patient Support.

## What if insurance denies my drug coverage?

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 appeals 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.

If you need help drafting an appeal or would like additional support in the appeal process, reach out to your care team. In some instances, patient advocacy organizations may be able to guide you through this process. A few organizations and support groups that you may find helpful are IgA Nephropathy Foundation, NephCure, etc. In addition, American Kidney Fund provides general information about health insurance and your rights as a patient. These organizations and websites are independently operated and are not managed by Novartis Pharmaceuticals Corporation. Novartis assumes no responsibility for any information they may provide.

You may be able to start treatment while the insurance company reviews your appeal. If eligible, the FABHALTA Bridge Program\* can help you get your medication when coverage is delayed or denied. Once your coverage is good to go, you can start using your \$0 Co-Pay Plus† Card to help cover your out-of-pocket costs.

\*Please see page 10 for full Terms and Conditions of the FABHALTA Bridge Program.

†Please see page 10 for full Terms and Conditions of the Co-Pay Plus Program.

## Important Safety Information (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.

**Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full Prescribing Information, including Boxed WARNING and Medication Guide.**

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules



# INSURANCE FAQs (continued)

## What if I have government insurance?

If you have government insurance and have questions about financial assistance, Novartis Patient Support can help by connecting you with Novartis Patient Assistance Foundation (NPAF). We also encourage you to reach out to your provider, patient organizations, or independent co-pay assistance foundations for support.



*If your coverage was denied, ask your care team about starting an appeal. Scan the QR code or click [here](#) for more information on the appeals process.*

## What if I don't have insurance?

If you aren't covered by health insurance, Novartis Patient Support can help by connecting you with Novartis Patient Assistance Foundation (NPAF). They'll tell you about eligibility, income, and out-of-pocket criteria that may vary by product. For additional information, please visit [www.PAP.Novartis.com](http://www.PAP.Novartis.com). To check eligibility and enroll in NPAF, please ask your doctor to submit a Start Form to Novartis Patient Support.

## How can I plan for long-term coverage?

Setting yourself up with consistent insurance coverage down the line is essential, and not all insurance plans offer the same coverage for chronic conditions and medications. If you're changing plans, pay attention to your specific coverage needs as you make your selection. Research and understand the differences between plans and how it could impact your out-of-pocket costs.

### Some things to keep in mind as you research available options:

- Sometimes, insurance companies require patients to try certain therapies before covering a specific treatment. It will be important to know this when selecting future insurance plans
- Understand what medications you are likely to cycle through, and which specialty pharmacies carry them
- Understand the extent of the coverage for your necessary medications

For more information, reach out to your care team for support. If you get your insurance through your employer, the HR or benefits team may be a good source of information for coverage details as well.

**For assistance with navigating the insurance process, contact Novartis Patient Support at [1-833-99FABHA \(1-833-993-2242\)](tel:1-833-99FABHA).**

## Important Safety Information (continued)

**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.

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

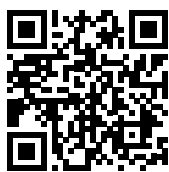
# USING YOUR CO-PAY PLUS\* OFFER

## \$0 Co-Pay Plus\* offer

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

## FABHALTA Bridge Program<sup>†</sup>

If you have private or commercial insurance, the FABHALTA Bridge Program<sup>†</sup> offers up to 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 the Co-Pay Plus\* Program, scan the QR code, [click here](#), or call [1-833-99FABHA \(1-833-993-2242\)](tel:1-833-99FABHA).

**\*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.

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).



# INSURANCE GLOSSARY

**As you start FABHALTA, you may come across new or confusing terms. This list can help you with insurance terms you might encounter along the way.**

## Appeal

A request for your insurance company to reconsider its decision about denying coverage of your medication.

## Benefits verification

This is when the insurance company reviews your coverage. This may identify a need for a prior authorization or what out-of-pocket costs may be for this prescription.

## Co-pay

A predetermined, fixed amount you pay for your medication after your health plan covers a portion of the total cost.

## Coinsurance

The percentage of covered medical costs you'll pay after you've reached your deductible.

## Deductible

The amount you pay for a prescription before your insurance starts to pay its portion of the cost.

## Formulary

A list of prescription medications covered by a prescription medication plan or another insurance plan offering prescription medication benefits.

## Government insurance

Insurance reserved for specific groups of people (eg, senior citizens, persons with low income, persons with disability, current military and their families, government employees, and some federally recognized Native American tribes) and funded by the government. Medicare, Medicaid, TRICARE, and the Veterans Health Administration program are all examples of government insurance.

## Out-of-pocket maximum

The most you will have to pay for prescription medications in a year. After you spend this amount on deductibles, co-pays, and coinsurance, your insurance plan covers 100% of the cost.

## Patient support program

A program that helps patients, caregivers, and health care professionals find support when they need it. Novartis Patient Support is one such program.

## Premium

The amount you pay for your health insurance every month.

## Prior authorization

An approval given by your insurance so your prescription is covered by your plan.

## Private insurance (sometimes called commercial insurance)

Insurance you buy individually or through your employer.

## Retail pharmacy

An independent or chain pharmacy that dispenses medications to the general public at retail prices.

## Specialty pharmacy

A pharmacy that carries medications that require specific handling and storage.

## Step therapy

A process by which insurers (public or private) require patients to take one or more alternative medications before they can access the medicine prescribed by their provider.

Please see additional Important Safety Information throughout and on pages 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# SUMMARY OF IMPORTANT INFORMATION FOR FABHALTA

## Approved Use

### What is FABHALTA?

FABHALTA is a prescription medicine used to reduce protein in the urine (proteinuria) in adults with primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly. It is not known if FABHALTA is safe and effective in children with IgAN.

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.

## 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 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
- 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 a 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 quickly.

Please see full [Prescribing Information](#), including **Boxed WARNING** and **Medication Guide**.

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# 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:**

- 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.

## **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 [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please see full **Prescribing Information**, including **Boxed WARNING** and **Medication Guide**.

 **FABHALTA**<sup>®</sup>  
(iptacopan) 200 mg capsules

# FIND MORE INFORMATION ABOUT FABHALTA

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 any of these helpful resources:

 <b>How FABHALTA Works</b> <p>Want to understand more about how FABHALTA works in your body? Explore more here:</p> <p><a href="https://www.fabhalta.com/IgAN/about-FABHALTA">FABHALTA.com/IgAN/about-FABHALTA</a></p>	 <b>Having Productive Conversations</b> <p>Need help preparing for your next doctor visit? Use this guide to feel confident in your approach.</p> <p><a href="https://www.fabhalta.com/IgAN/doctor-discussion-Guide">FABHALTA.com/IgAN/doctor-discussion-Guide</a></p>
 <b>Novartis Patient Support</b> <p>Novartis Patient Support can help support you every step of the way. Sign up for Novartis Patient Support today.</p> <p><a href="https://support.FABHALTA.com">support.FABHALTA.com</a></p>	 <b>More FABHALTA Information</b> <p>Want to stay connected on FABHALTA-related topics? Sign up now to receive important email updates.</p> <p><a href="https://www.fabhalta.com/IgAN/sign-up">FABHALTA.com/IgAN/sign-up</a></p>
 <b>Want to share your FABHALTA story?</b> <p>Help inspire and empower others with IgAN by sharing your experiences.</p> <p>Call <a href="tel:1-877-879-0245">1-877-879-0245</a> (8 AM–5 PM PST) or email <a href="mailto:info@voices-of-inspiration.com">info@voices-of-inspiration.com</a></p>	

## Approved Use

### What is FABHALTA?

FABHALTA is a prescription medicine used to reduce protein in the urine (proteinuria) in adults with primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly. It is not known if FABHALTA is safe and effective in children with IgAN.

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.

## 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 12 and 13. Please see full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

