FABHALTA® (iptacopan) 200 mg capsules

*To **slow kidney function decline** in adults with primary **IgAN** at risk of disease worsening*



Patient portrayal.

IgAN, immunoglobulin A nephropathy.

The first and only FDA-approved oral IgAN treatment that targets the alternative complement pathway, a part of the immune system

Approved Use

What is FABHALTA?

FABHALTA is a prescription medicine used to slow kidney function decline in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease getting worse.

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

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 cause death if not recognized and treated early.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

ARE YOU TAKING MULTIPLE SUPPORTIVE CARE TREATMENTS AND*

CONCERNED ABOUT YOUR KIDNEY FUNCTION LOSS?

Slowing kidney function decline is vital for adults with IgAN

IgAN is a chronic disease that may worsen over time and impact kidney function, which is how well the kidneys are working. Signs that IgAN is getting worse include ongoing high levels of protein in urine (proteinuria) and loss of kidney function.

In a study of 655 adult patients with primary IgAN

~1 in 6 lost

50% or more of their kidney function (based on eGFR) within 3 years of diagnosis



This was from a study that looked back at patient records from a California healthcare system in those diagnosed with IgAN. The purpose of this study was to assess multiple kidney outcomes. At the start of study, patients were on different treatments; 70% were on an ACEi or ARB with limited use of other therapies. At the start of study, the average eGFR was 59.9 mL/min/1.73 m^2 and average UPCR 2.5 g/g.

It can be reassuring to know that you're not alone. It's normal to feel frustrated or discouraged, especially when you're doing all you can to manage your IgAN.

If you're living with ongoing high levels of proteinuria and kidney function loss, it may be time to consider a different approach.

*Supportive care can involve lifestyle changes (limiting dietary sodium, exercising regularly, maintaining a healthy weight, and avoiding tobacco), blood pressure management, and treatment with an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB) and a sodium/glucose cotransporter 2 inhibitor (SGLT2i).

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 cause death 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.

TO SLOW KIDNEY FUNCTION DECLINE IN ADULTS WITH PRIMARY IgAN AT RISK OF DISEASE WORSENING

FABHALTA: A TARGETED APPROACH THAT MAY OFFER WHAT YOU ARE LOOKING FOR

Oral dosing with or without food
Take 1 capsule **twice** a day

A targeted IgAN treatment
The only oral IgAN treatment targeting the alternative pathway within the complement system, a part of the immune system that is thought to contribute to IgAN

Backed by clinical evidence
Tested in a large clinical study of 477 adults with primary IgAN over 24 months

"My doctor explained that FABHALTA can help slow kidney function decline. Having a treatment that works for me makes all the difference."

— Sarah is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.



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 cause death 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.

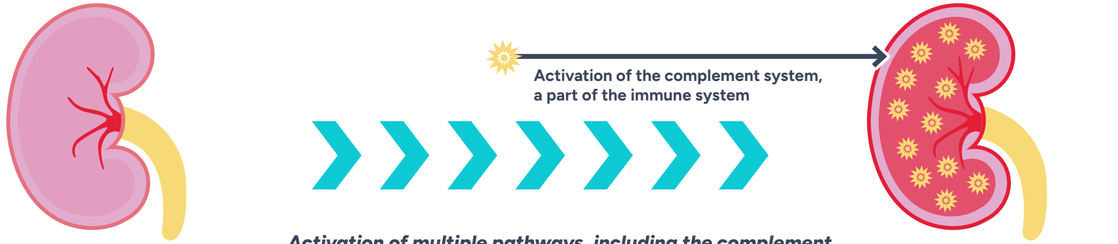
Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

HOW THE ALTERNATIVE COMPLEMENT PATHWAY AFFECTS YOUR KIDNEYS IN IgAN

The alternative complement pathway is a part of your immune system that helps protect your body by "complementing" or enhancing your immune system in fighting infections.

In IgAN, IgA antibodies that are supposed to fight infections become defective. This causes your immune system to work against itself. Unwanted IgA antibodies build up in your kidneys, leading to the activation of the complement system and other pathways, which can lead to kidney-related issues in IgAN.



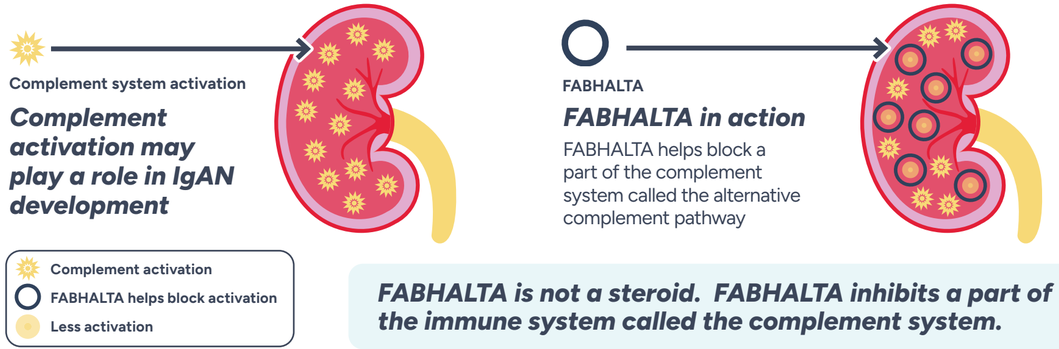
DID YOU KNOW?

Part of your immune protection involves the alternative complement pathway. In IgAN, it may play a role in how your disease develops.

FOR ADULTS WITH PRIMARY IgAN AT RISK OF DISEASE WORSENING

FABHALTA: A FIRST-OF-ITS-KIND TARGETED IgAN TREATMENT

FABHALTA is the first and only FDA-approved oral treatment in IgAN that targets the alternative complement pathway



FABHALTA is not a steroid. FABHALTA inhibits a part of the immune system called the complement system.

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 cause death if not recognized and treated early.
  - Vaccines do not prevent all infections caused by encapsulated bacteria. **Tell your health care provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
    - Fever with or without shivers or 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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IN ADULTS WITH PRIMARY IgAN AT RISK OF DISEASE WORSENING

TESTED IN A LARGE CLINICAL STUDY OF 477 ADULTS WITH IgAN

APPLAUSE-IgAN was a phase 3 clinical study in adults with primary IgAN: FABHALTA was compared to placebo (sugar pill).

Who was studied?

Adults with biopsy-proven IgAN who:

- Had elevated proteinuria, UPCR ≥1 g/g (UPCR is a test to measure amount of protein leaking into urine collected over 24 hours)
- Were on a stable dose of ACEi/ARBs at a maximally tolerated dose with or without other background therapies before and during the study

How was the study done?

FABHALTA 200 mg twice daily

Placebo (sugar pill) twice daily

Interim analysis at 9 months

- Included the first 125 patients taking FABHALTA vs 125 patients taking placebo
- The primary goal was to compare the change in UPCR at 9 months to the start of the study (baseline):
  - 44% proteinuria reduction with FABHALTA vs 9% with placebo

Final analysis at 24 months

- Included 238 patients taking FABHALTA and 239 patients taking placebo
- The primary goal was to study the rate of kidney function decline over 24 months as measured by eGFR

All efficacy analyses were done in participants with eGFR ≥30 mL/min/1.73 m^2.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; UPCR, urine protein-to-creatinine ratio.

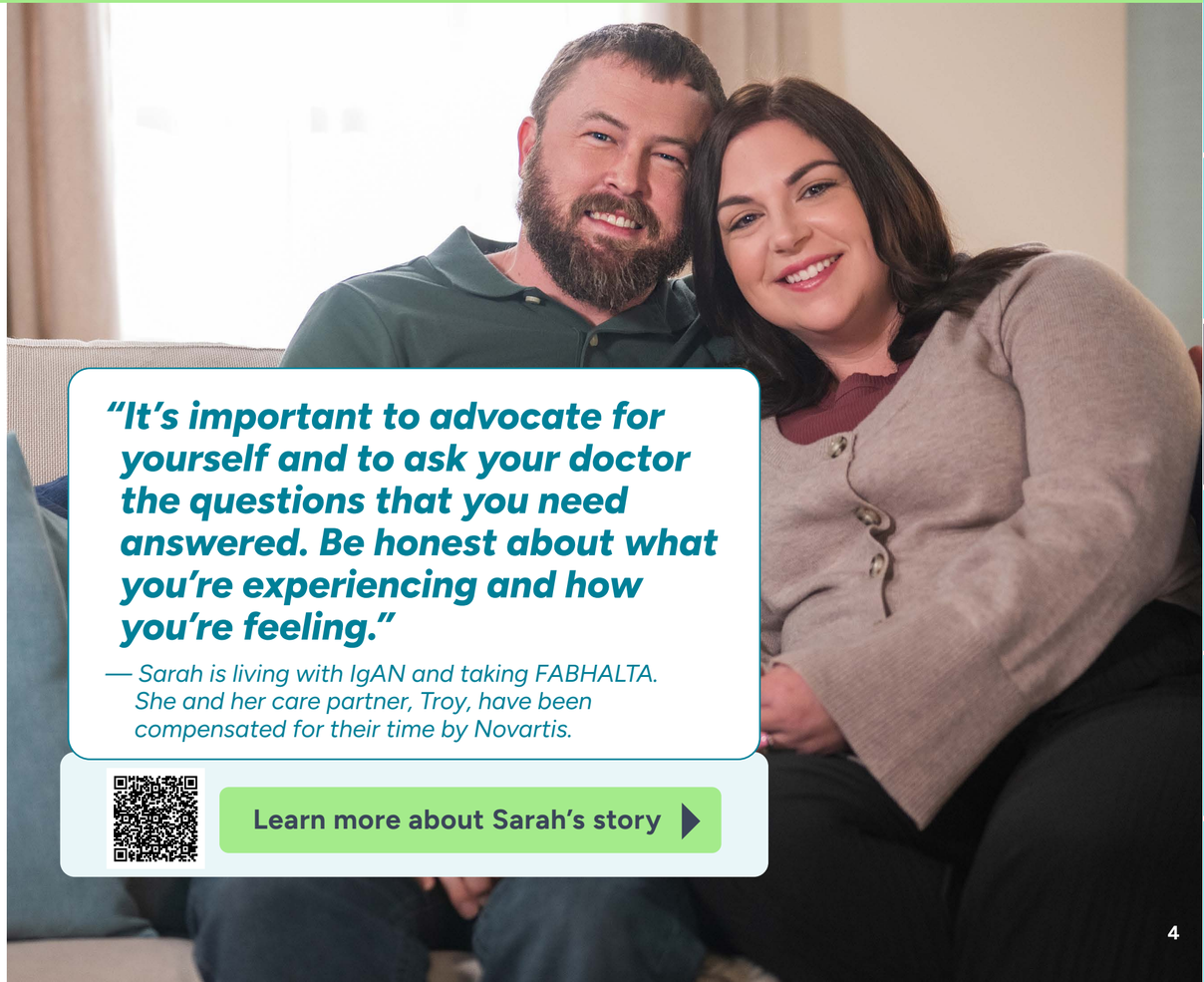
Important Safety Information (continued)

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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"It's important to advocate for yourself and to ask your doctor the questions that you need answered. Be honest about what you're experiencing and how you're feeling."

— Sarah is living with IgAN and taking FABHALTA. She and her care partner, Troy, have been compensated for their time by Novartis.

Learn more about Sarah's story

WHY YOUR eGFR MATTERS

Estimated glomerular filtration rate helps show how well your kidneys are functioning.

HIGHER eGFR
=
HIGHER KIDNEY FUNCTION

LOWER eGFR
=
LOWER KIDNEY FUNCTION

eGFR was studied in patients who received FABHALTA or placebo to see how the treatment worked on a person's kidney function over time.

Changes in your eGFR over time show how fast your kidneys are losing function. Kidney function decline over time is reflected as a negative value.

eGFR can be tracked over time to calculate the average yearly change
- A negative number closer to zero indicates slower decline in kidney function
- A negative number further from zero indicates faster decline in kidney function

"It's important for you to be aware of your numbers so you can see where it's trending."

– Sarah is living with IgAN and taking FABHALTA, compensated for her time by Novartis.



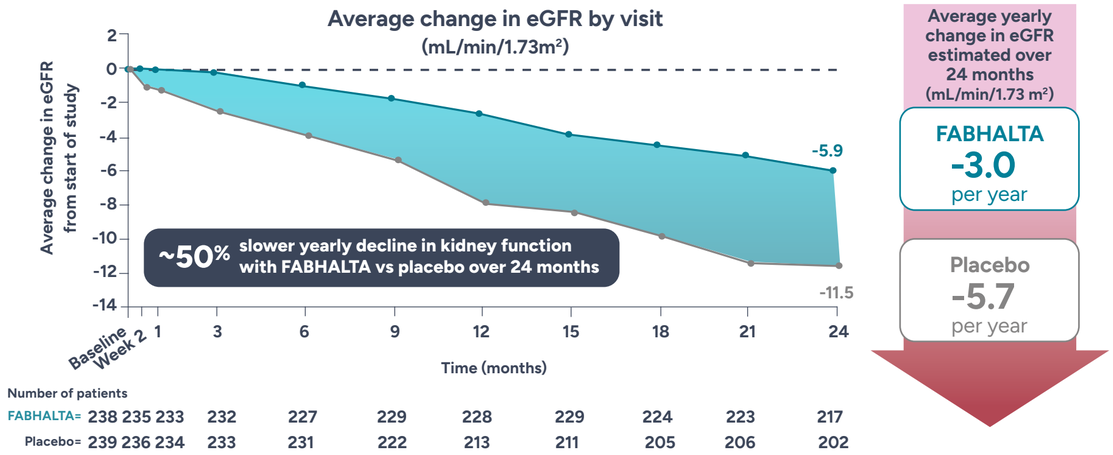
Important Safety Information (continued)

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 written information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria.

IN ADULTS WITH PRIMARY IgAN AT RISK OF DISEASE WORSENING

FABHALTA HELPED PRESERVE KIDNEY FUNCTION BETTER THAN PLACEBO



The numbers shown above tell you how many people were included in the study results at each point in time.

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:
- Make sure 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 page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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ONGOING HIGH LEVEL OF PROTEIN IN URINE (PROTEINURIA) MAY BE A SIGN OF KIDNEY DAMAGE

One common way to measure proteinuria is a test called urine protein-to-creatinine ratio (UPCR). UPCR helps your health care team monitor how much protein leaks into your urine. UPCR can be measured in a couple of ways by:

- Collecting urine over a 24-hour period, called 24-hour UPCR
- Testing a single urine sample from your first urination of the day (called the first morning void, or FMV)

A treatment goal in IgAN is to lower proteinuria. If proteinuria levels remain high, it is an indicator that IgAN may not be properly managed. If it's increasing over time, it may be getting worse.

DID YOU KNOW?	***According to expert guidelines for IgAN, keeping proteinuria below 0.5 g/day is the goal.***

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 start FABHALTA.

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

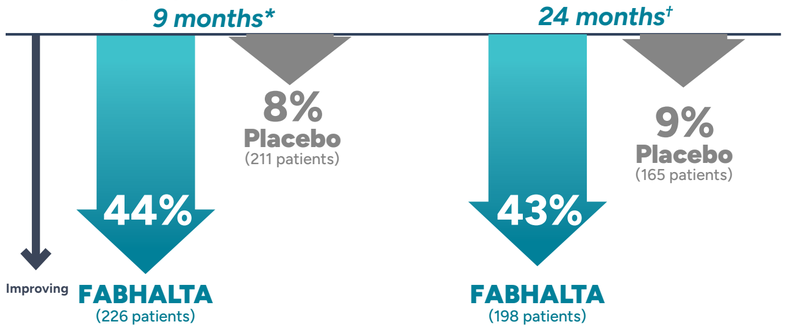
- Have an infection or fever.
- Have liver problems.

IN ADULTS WITH PRIMARY IgAN AT RISK OF DISEASE WORSENING

SUBSTANTIAL PROTEINURIA REDUCTION WITH FABHALTA

Change in proteinuria levels measured by 24-hour UPCR at 9 and 24 months compared to start of the study

Final analysis proteinuria reduction at:



UPCR, urine protein-to-creatinine ratio.

*Percent reduction was calculated by comparing average proteinuria levels at the start of the study to average proteinuria levels at month 9.

†Percent reduction was calculated by comparing average proteinuria levels at the start of the study to average proteinuria levels at month 24.

Important Safety Information (continued)

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

- 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.

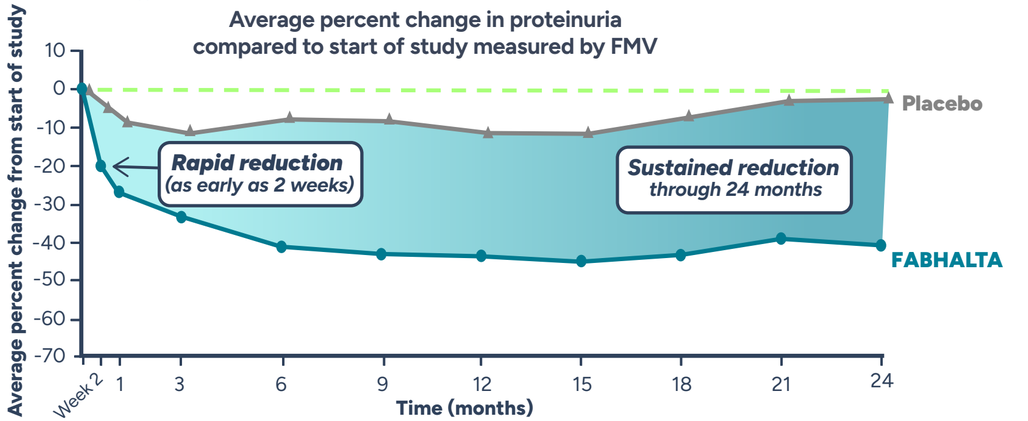
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IN ADULTS WITH PRIMARY IgAN AT RISK OF DISEASE WORSENING

FAST AND LASTING PROTEINURIA REDUCTION WITH FABHALTA

Proteinuria was also studied by measuring UPCR in first urination of the day, called first morning void (FMV)



N=	236	221	223	222	214	220	209	209	200	201	193 ● FABHALTA
N=	234	223	222	222	214	202	193	183	172	169	158 ▲Placebo

The numbers shown above tell you how many people were included in the study results at each point in time.

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.

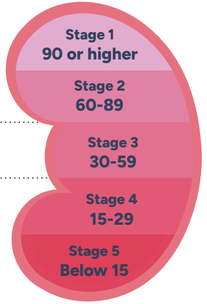
NOW YOU KNOW

eGFR & PROTEINURIA ARE AMONG THE KEY MEASURES USED TO EVALUATE YOUR IgAN

1 eGFR = estimated glomerular filtration rate

Chronic kidney disease (CKD) is categorized into 5 stages based primarily on your estimated glomerular filtration rate (eGFR) and the presence of kidney damage (such as protein in the urine or proteinuria).

1. Normal function with slight kidney damage
2. Mild loss of function
3a. Mild to moderate loss of function
3b. Moderate to severe loss of function
4. Severe kidney damage, loss of function
5. Advanced kidney disease or end-stage kidney failure



2 Proteinuria = protein in urine

Proteinuria is the term for what happens when protein leaks into your urine. It is an important marker for kidney disease activity. Foamy urine can be one of the key symptoms.

The less protein in your urine, the better. The KDIGO 2025 guidelines recommend proteinuria below 0.5g per day and, ideally, below 0.3g per day.



DID YOU KNOW?

Higher eGFR number indicates better kidney function
High proteinuria number increasing over time may indicate IgAN worsening

Important Safety Information (continued)

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.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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SAFETY PROFILE OF FABHALTA

The most common side effects of FABHALTA in adults include:

- Headache
- Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)
- Diarrhea
- Feeling dizzy
- Pain in the stomach (abdomen)
- Infections (bacterial and viral)
- Nausea
- Rash

Because of the risk of serious infections, FABHALTA is only available through a Risk Evaluation and Mitigation Strategy (REMS) program that requires vaccinations.

See page 9 for more information on the risk of serious infections and the need for vaccinations.
See page 10 for more on the FABHALTA REMS program.

FABHALTA may cause serious side effects, including 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.

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.

Important Safety Information (continued)

What are the possible side effects of FABHALTA? (continued)

The most common side effects of FABHALTA in adults include:

- Headache
- Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)
- Diarrhea
- Feeling dizzy
- 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.

FABHALTA CAN FIT INTO YOUR DAILY ROUTINE

One capsule. Twice a day.

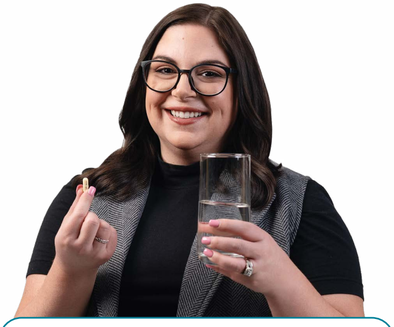
- Each capsule contains 200 mg of FABHALTA
- Take 1 capsule twice a day with or without food
- Swallow the capsules whole
- **Do not** open, break, or chew capsules

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. Then take your next dose at your regularly scheduled time.

Take FABHALTA exactly as your health care provider tells you. **Do not** change the dose or stop taking FABHALTA unless your health care provider tells you.

DID YOU KNOW?	***You can take FABHALTA with or without food.*** ***Ask your health care team if FABHALTA could be right for you.***



"I'm happy that FABHALTA is a capsule, and as a mom with 2 kids, I can fit it into my schedule."

— Sarah is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.

Important Safety Information (continued)

What are the possible side effects of FABHALTA? (continued)

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 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

WHY YOU NEED CERTAIN VACCINATIONS BEFORE STARTING FABHALTA

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.

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 cause death 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 *Streptococcus pneumoniae* infection
Meningococcal	Helps protect you from the risk of meningitis caused by *Neisseria meningitidis* infection

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.

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

Vaccines do not prevent all infections caused by encapsulated bacteria.

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

- Fever with or without shivers or 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

PREPARING TO START FABHALTA: VACCINATIONS AND TIMING

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:

Has your doctor confirmed that your required vaccinations are complete?

- **YES** → If you have completed your required vaccinations and 2 weeks have passed,* you can begin taking FABHALTA right away
- **NO**
  - If you have not completed or updated your vaccinations before starting FABHALTA:
    1. Complete or update the required vaccinations listed on page 9
    2. Wait at least 2 weeks
    3. Start FABHALTA
  - If FABHALTA needs to be started right away, but you haven't completed or updated your vaccinations, you should:
    1. Begin treatment with FABHALTA and antibiotics. You will take these antibiotics for as long as your health care provider tells you
    2. Continue to complete or update required vaccinations as soon as possible

While taking FABHALTA, you should be revaccinated according to current medical guidelines for encapsulated bacteria. Your health care provider or Novartis Patient Support™ 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.

For eligible patients, Novartis Patient Support can help schedule in-home administration appointments, find local vaccination locations, and offer guidance on accessing existing vaccination records.

Check offers here

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (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 written information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria.
- Make sure 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 as discussed below.

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 health care provider or get emergency medical assistance immediately.

To learn more about the FABHALTA REMS program, please call the REMS helpline at 1-866-201-3101 between 8:00 AM and 4:00 PM ET or visit **FABHALTA-REMS.com**.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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"My doctor told me I would have to get certain vaccinations before I started FABHALTA because it increases the risk for certain infections. I got them done and was happy to start FABHALTA."

— Sarah is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.

Connect with a Patient & Community Liaison to learn more about IgAN and FABHALTA

APPROVED USE AND IMPORTANT SAFETY INFORMATION FOR FABHALTA (IPTACOPAN)

Approved Use

What is FABHALTA?

FABHALTA is a prescription medicine used to slow kidney function decline in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease getting worse.

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

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

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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. **Tell your health care provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
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    - 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 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 written information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria.
- Make sure 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 start 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
- Feeling dizzy
- 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 full Prescribing Information, including Boxed WARNING and Medication Guide.

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ACCESS TO FABHALTA WITHIN REACH

Check latest coverage and costs information to get started on FABHALTA.

FABHALTA access in 3 steps

	1. Gain insurance approval	2. Pay for FABHALTA	3. Receive FABHALTA
What to expect	Your doctor's office will submit a prior authorization to your insurance company. Most are approved within a few weeks.	There are programs available to help you pay for FABHALTA.	A specialty pharmacy will reach out to coordinate shipment with you. • You will receive a 30-day supply • The specialty pharmacy should call you to reschedule your refill 5 to 10 days before you run out • If you are running low on your medication and haven't heard from your specialty pharmacy, call them ASAP
What you can do	Call your doctor's office if you don't hear anything after 2 weeks.	Ask your pharmacist about affordability programs you may qualify for.	**You must answer the phone or return pharmacy phone calls to schedule your FABHALTA delivery.** **Specialty pharmacies that dispense FABHALTA:** • Biologics by McKesson (800-850-4306) • CareMed‡ (877-227-3405) Please make sure that the specialty pharmacy's phone number has not been blocked by your phone or carrier. Please make sure to check your voicemail and give them a call back. For patients in Puerto Rico, please contact Medplus Solutions (787-523-3888)
Available support	The FABHALTA Bridge Program offers up to 12 months of FABHALTA for free for privately insured eligible patients while insurance coverage is pursued. See terms and conditions on page 13.	You may be eligible for the $0 Co-Pay Plus offer. See terms and conditions on page 13.	A dedicated Novartis Patient Support (NPS) team will provide ongoing support throughout your FABHALTA treatment.

90%
of all prior authorizations are approved for FABHALTA IgAN*

96%
of IgAN patients paid $10 or less per month†

Novartis does not recommend or require the use of any particular pharmacy.
Data on file. FABHALTA Novartis Hub Patient Services and Specialty Pharmacy payer coverage outcome data. Novartis Pharmaceuticals Corp; 2026.

*Between August 2023 and March 2026.

† Specialty pharmacy data from April 2025 to March 2026 for 3,019 prescriptions which represents approximately 99% of total prescriptions. For remaining people, the out-of-pocket cost for the product varies and may be as high as the total cost of the product.

‡CareMed is a subsidiary of Onco360.

The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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YOUR CONDITION MAY BE RARE, BUT SUPPORT ISN'T

Novartis Patient Support can help you every step of the way

Now that you've been prescribed FABHALTA, you have support in your corner. Start, stay, and save on FABHALTA with the help of Novartis Patient Support.

Gain Insurance Support

Novartis Patient Support will work with your provider to help navigate insurance coverage for FABHALTA.

Financial Support

If you have private insurance, you may be eligible for the **$0 Co-Pay Plus*** offer for FABHALTA. If you have private insurance and are eligible, the **Bridge Program**† offers up to 12 months of FABHALTA for free while insurance coverage is pursued.

Get FABHALTA

Your specialty pharmacy may help with medication education, insurance approval, affordability programs, and refill reminders.

- If you need help getting your vaccinations before starting FABHALTA, the Vaccination Support program provides in-home vaccinations or guided navigation to help find a vaccination location near you or provide guidance on accessing existing records.

Sign up for Novartis Patient Support

1. **Call 833-99FABHA (833-993-2242)**, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays. Your dedicated Novartis Patient Support team can then help you sign up

There are a few ways to start getting support:

2. Sign up online at **support.FABHALTA.com**
3. **Ask your health care provider** to help sign you up at your next appointment

The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients.

NEED FINANCIAL SUPPORT? WE'RE HERE TO HELP.

$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. The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients.

FABHALTA Bridge Program†

If you have private or commercial insurance, the FABHALTA Bridge Program 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 Novartis Patient Support, Click here or call 833-99FABHA (833-993-2242).

***Co-Pay Plus:** Limitations apply. Patients with private 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 the 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 this Program and discontinue support at any time without notice.

†**Bridge Program:** The Bridge Program applies to FABHALTA only. Eligible patients must have private insurance and a valid prescription for FABHALTA, and a prior authorization or an initial denial of coverage. Program requires the submission of a prior authorization or an appeal of the coverage denial within the first 45 days of enrollment to remain eligible. Program provides FABHALTA for free to eligible patients for up to [12 months], or until they receive insurance coverage approval, whichever occurs earlier. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Patients may be asked to reverify insurance coverage status during the course of the Program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional limitations may apply. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this Program without notice.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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PATIENT & COMMUNITY LIAISONS ARE HERE TO SUPPORT YOU

You have a dedicated team in your corner

Living with a rare condition can feel isolating. Patient & Community Liaisons (PCLs) provide education, resources, and personalized support to help you understand and navigate your disease journey.

FABHALTA PCLs are here to:

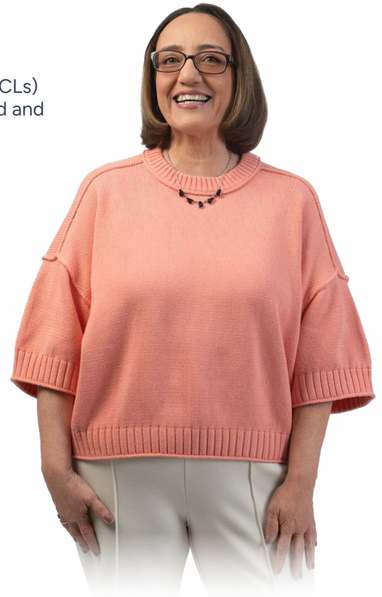
- Engage with you and others like you affected by your condition. PCL engagement also extends to care partners and local community advocacy partners
- Educate the community and help affected people access helpful information
- Build relationships with local community and advocacy groups to help identify opportunities for support and connection within the community

PCLs do not provide medical advice.

Reach out to us at 1-877-FABPCLs (877-322-7257)

We look forward to connecting with you!

Grow your support system by connecting with a PCL today



Claudia is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules



"When I found out that FABHALTA was helping to slow kidney function decline, it felt so empowering—I'm on a treatment that works the way it's supposed to for me."

—Sarah is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.

Ready to talk to your doctor about FABHALTA? get your Doctor Discussion Guide here.

THE POWER OF SUPPORT & SELF-ADVOCACY

Make the most of tools and organizations that are here to help you

If you or a loved one has been diagnosed with IgAN, it's reassuring to know that resources are available to support you before, during, and after any appointments. By taking advantage of these tools, you can better communicate with the care team so they can support you through your journey.

There's a wide range of tools to help you advocate for yourself. You could:

- Watch Sarah share her experiences with IgAN
- Talk to a PCL to learn more about IgAN and FABHALTA
- Use the Doctor Discussion Guide to help prepare for your doctor's visit
- Once prescribed FABHALTA, enroll in Novartis Patient Support for support every step of the way

Connecting with a community

When dealing with a rare disease, support from a community can make a difference. People who've been where you are now can help you. They can share personal experiences with others in the IgAN community. What's more, there are groups to support you operating at national, local and social levels.

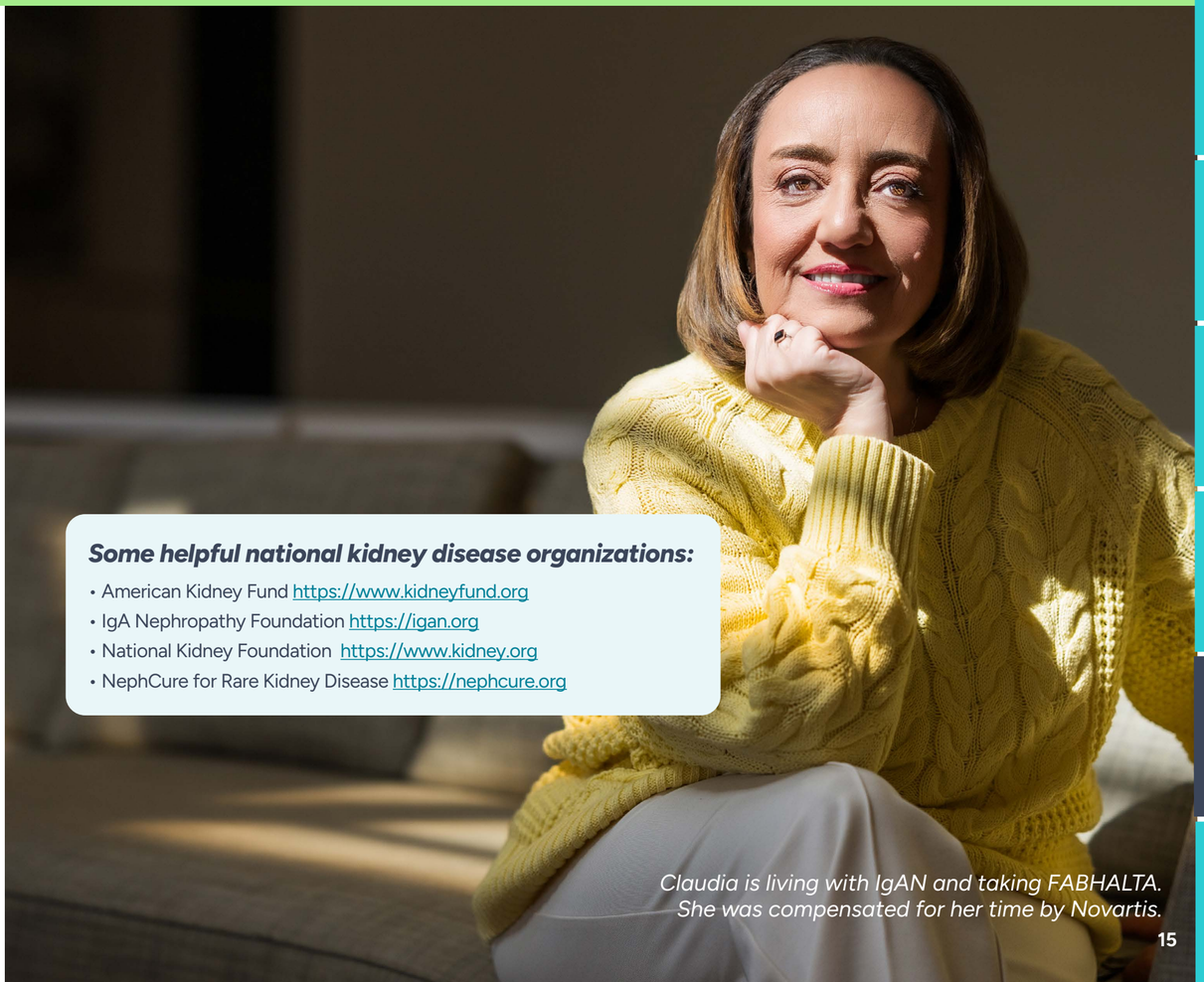
Help with vaccinations

If you need help getting your vaccinations before starting FABHALTA, the Vaccination Support program provides in-home vaccinations or guided navigation to help find a vaccination location near you or provide guidance on accessing existing records.

Download helpful resources

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Some helpful national kidney disease organizations:

- American Kidney Fund https://www.kidneyfund.org
- IgA Nephropathy Foundation https://igan.org
- National Kidney Foundation https://www.kidney.org
- NephCure for Rare Kidney Disease https://nephcure.org

Claudia is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.

COMMON IgAN TERMS YOU MAY HEAR

ACEi/ARB

Angiotensin converting enzyme inhibitors (ACEi) and angiotensin receptor blockers (ARB) are two of the most commonly prescribed medicines for managing high blood pressure in IgAN.

Alternative complement pathway

This is a part of the immune system that helps defend your body against unwanted substances.

Antibodies

Proteins produced by your immune system that protect your body from unwanted substances like bacteria, viruses, and toxins.

Appeal

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

Autoantibodies

Antibodies that mistakenly react to and target your own body. This could trigger autoimmune damage to different parts of the body, including the kidneys.

Autoimmune disease

When your body's natural defense system mistakenly attacks healthy cells.

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.

Biopsy

A medical procedure that uses cells, tissue, or fluid from your body to diagnose a medical condition.

Bridge program

If eligible, a bridge program can help you get your medication when coverage is delayed or denied.

CKD

Chronic kidney disease (CKD) is the gradual, ongoing loss of kidney function.

Co-insurance

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

Co-pay

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

Corticosteroids

Corticosteroids (also called glucocorticoids or steroids) are prescription medications that can help reduce inflammation in your body. They are a type of immunosuppressant medication used to suppress your immune system.

Deductible

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

Dialysis

A procedure during which a machine outside the body is used to remove waste products and excess fluid from the blood when the kidneys stop working properly. Treatment usually takes about 3 to 5 hours each time and is done three times a week. The most common type of dialysis is called hemodialysis.

eGFR

Estimated Glomerular Filtration Rate is a number which measures your level of kidney function and current stage of kidney disease.

First morning void (FMV)

First urination of the day.

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.

Hematuria

Blood in your urine. "Gross hematuria" means that the blood is visible to the naked eye. "Microscopic hematuria" is when blood is present, but can only be seen under a microscope or found using a urine test (urinalysis).

Immunoglobulin A (IgA)

Immunoglobulin A is an antibody, a protein found in your blood, that's part of your immune system. Your body makes IgA and other types of antibodies to help fight off sickness.

Kidney transplant

Surgically implanting a kidney from a living or deceased donor into a person with kidney failure or end-stage kidney disease.

Nephrologist

A doctor who diagnoses and treats kidney conditions and diseases.

Novartis Patient Support

Personalized assistance that can help you start, stay, and save on treatment. See details on page 13.

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 co-insurance, your insurance plan covers 100% of the cost. See details on page 13.

Pathologist

A doctor who analyzes human tissue, blood, bodily fluids, or cells to diagnose and monitor diseases.

Patient & Community Liaisons (PCLs)

PCLs provide education, resources, and personalized support to help you understand and navigate your disease journey. PCLs do not provide medical advice. See page 14.

Physician assistant (PA)

A medical professional who assists doctors in diagnosing and treating patients.

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.

Proteinuria

Proteinuria means an increased level of protein in the urine, and may be a sign of kidney damage.

Renal

Anything pertaining to the kidneys.

Risk Evaluation And Mitigation Strategy (REMS)

REMS is a drug safety program required for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. Your health care provider will need to be certified in the FABHALTA REMS program, so that they may prescribe you FABHALTA. You do not have to enroll in anything yourself.

Specialty pharmacy

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

Urine protein-to-creatinine ratio (UPCR)

A measure of the amount of protein leaking into your urine.

Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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DISCOVER HOW FABHALTA MAY HELP

Take the next step for your IgAN

Learn more about FABHALTA results

Oral dosing with or without food
One capsule twice a day can fit in your daily routine.

FABHALTA inhibits a part of the immune system called the alternative complement pathway. FABHALTA is not a steroid.

Backed by clinical evidence
Tested in a large clinical study of 477 adults with primary IgAN over 24 months.

Personalized education & support throughout your journey

- **Learn more about IgAN & FABHALTA**
  Call a Patient & Community Liaison at 877-322-7257
- **Help you start, stay, and save on FABHALTA**
  Call Novartis Patient Support at 833-993-2242

Broad and established coverage*
96% of IgAN patients paid $10 or less per month.†

*The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients.

†Specialty Pharmacy data from April 2025 to March 2026 for 3,019 prescriptions which represents approximately 99% of total prescriptions. For remaining people, the out-of-pocket cost for the product varies and may be as high as the total cost of the product.

"Taking a medication like FABHALTA that's working to help slow kidney function decline is important to me."

— Sarah is living with IgAN and taking FABHALTA. She was compensated for her time by Novartis.



Approved Use

What is FABHALTA?

FABHALTA is a prescription medicine used to slow kidney function decline in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease getting worse.

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

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 cause death if not recognized and treated early.

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Please see additional Important Safety Information throughout and on page 11, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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