FABHALTA® (iptacopan) 200 mg capsules

To reduce proteinuria in adults with primary IgAN at risk of their disease progressing quickly

TAKE A DIFFERENT PATH FOR YOUR IgAN

Patient portrayal.

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 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

YOU MAY BE CONCERNED WITH WHERE YOUR IgAN IS HEADING

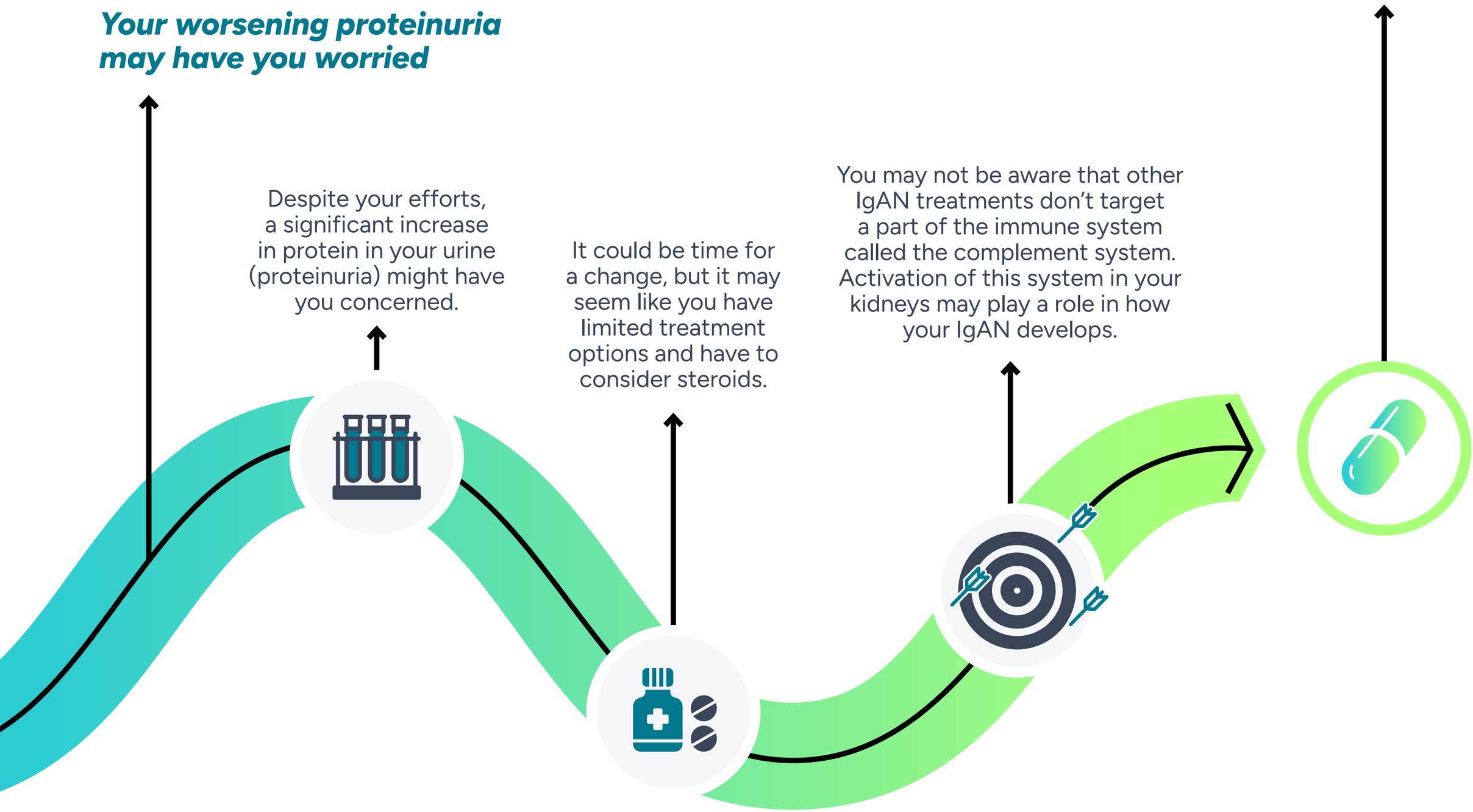
Your worsening proteinuria may have you worried

Despite your efforts, a significant increase in protein in your urine (proteinuria) might have you concerned.

It could be time for a change, but it may seem like you have limited treatment options and have to consider steroids.

You may not be aware that other IgAN treatments don't target a part of the immune system called the complement system. Activation of this system in your kidneys may play a role in how your IgAN develops.

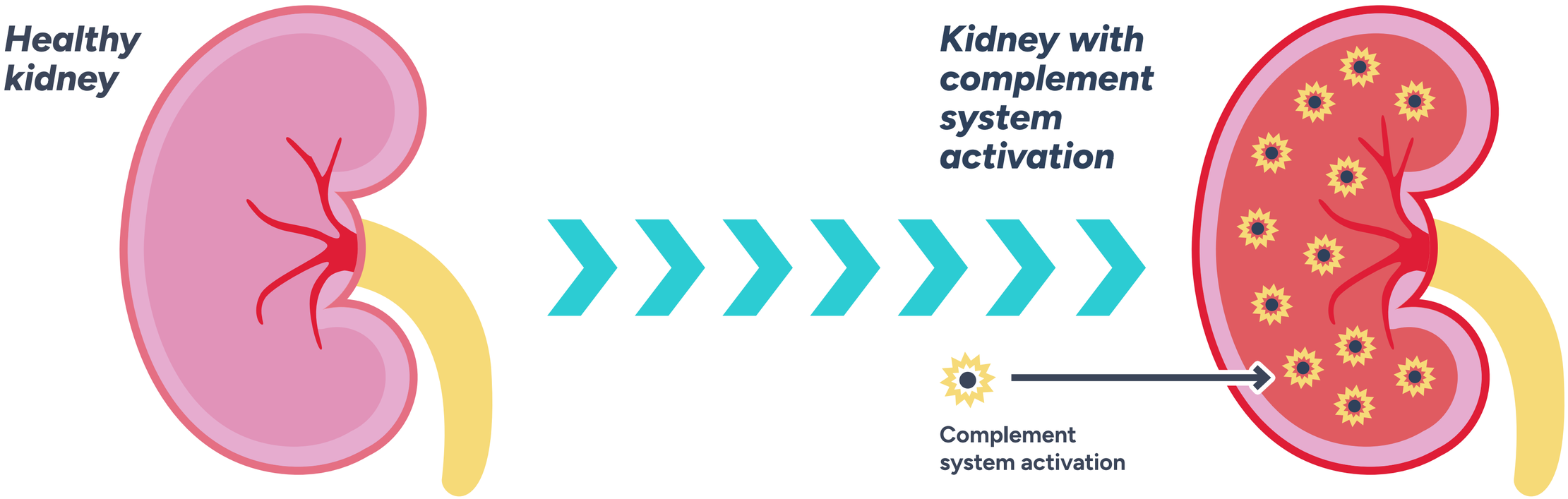
IT'S TIME TO CONSIDER A DIFFERENT APPROACH



UNDERSTANDING YOUR IgAN

IgAN occurs when IgA antibodies that are supposed to fight infections become defective and cause your immune system to work against itself.

In IgAN, unwanted IgA antibodies build up in your kidneys, leading to the activation of multiple pathways **including a part of your immune system called the complement system.**



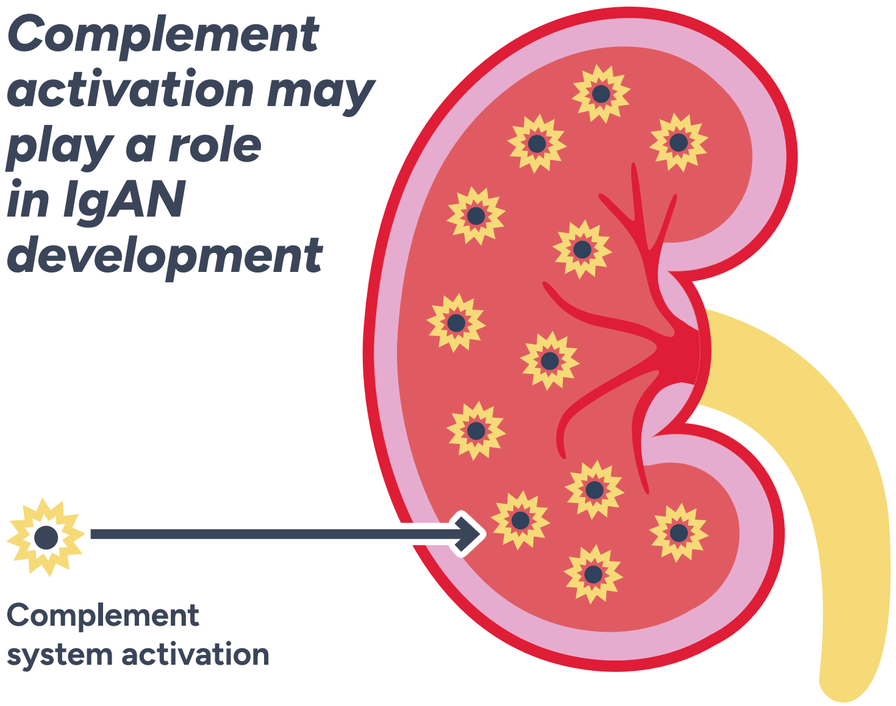
Activation of multiple pathways, including the complement system, may result in inflammation, kidney injury, and scarring.

Please see Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

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

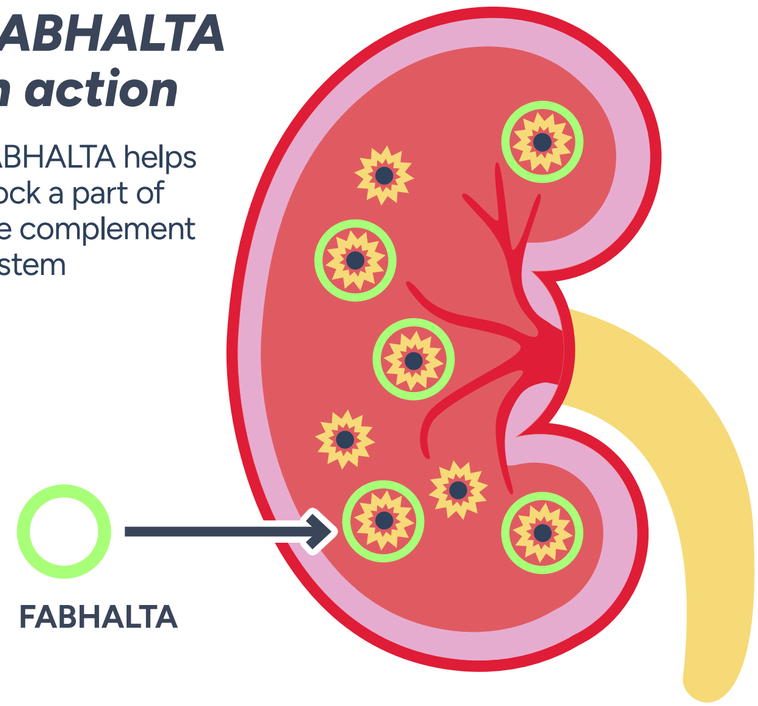
FABHALTA is the first and only FDA-approved treatment for adults with primary IgAN at risk of their disease worsening quickly, that targets the complement system.

Complement activation may play a role in IgAN development



FABHALTA in action

FABHALTA helps block a part of 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 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.

Please see additional Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

FABHALTA WAS STUDIED IN ADULTS WITH IgAN

The APPLAUSE-IgAN trial is a phase 3, placebo-controlled clinical study in adults with primary IgAN that studied the percentage reduction in urine protein-to-creatinine ratio, or UPCR, a test used to measure protein in urine. In this study, urine samples were collected over 24 hours, with results from the start of the study compared against those at Month 9.

Who was studied?

Participants with biopsy-proven IgAN with elevated proteinuria (UPCR ≥1 g/g) who were on a stable dose of maximally tolerated blood pressure medications (ACEi/ARB) with or without other background therapies before and during the study.

How was the study done?

Efficacy results were analyzed* after the first 125 participants taking FABHALTA (200 mg twice daily) and 125 participants taking placebo (sugar pill) received 9 months of study treatment.

*Analysis was of participants with eGFR ≥30 mL/min/1.73 m^2 at the start of the study.
ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

Important Safety Information (continued)

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

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria**, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life threatening or fatal if not recognized and treated early.
  - If you have not completed your vaccinations and FABHALTA must be started right away, you should receive the required vaccinations as soon as possible.
  - If you have not been vaccinated and FABHALTA must be started right away, you should also receive antibiotics to take for as long as your health care provider tells you.
  - 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

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FABHALTA® (iptacopan) 200 mg capsules

FABHALTA SUBSTANTIALLY REDUCED PROTEINURIA

IN ADULTS WITH PRIMARY IgAN AT RISK OF THEIR DISEASE WORSENING QUICKLY

Primary Study Objective

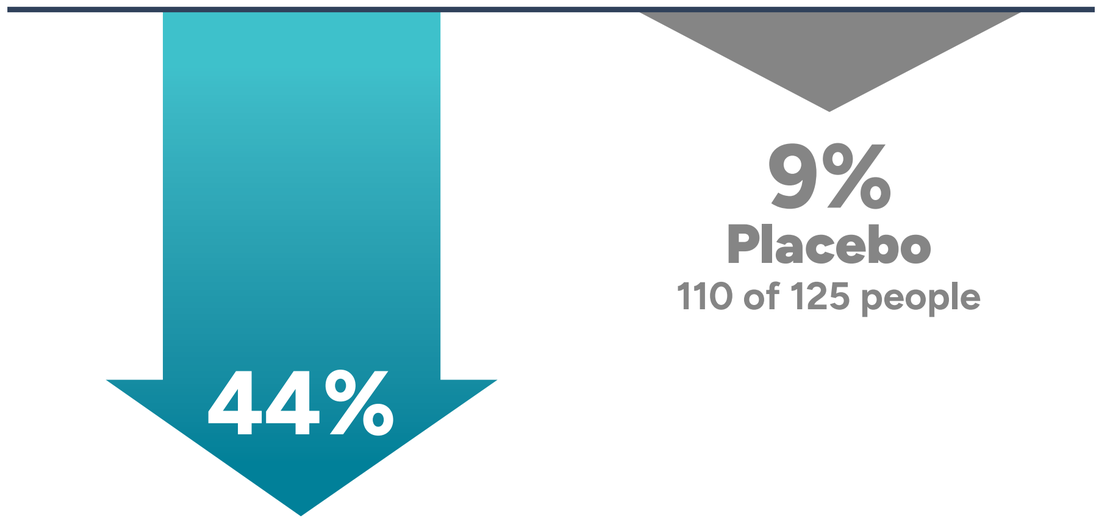
FABHALTA was shown to substantially reduce proteinuria levels at 9 months compared to placebo (sugar pill).

FABHALTA is used to reduce proteinuria in adults with primary IgAN at risk of their disease worsening quickly.

*Percent reduction was calculated by comparing average proteinuria levels at the start of the study and at Month 9; Results for patients requiring rescue treatments for IgAN were assumed to relate to disease worsening. As of Month 9, 7 (5.6%) patients in the placebo (sugar pill) arm and 0 patients in the FABHALTA arm received rescue treatment for IgAN.

Rescue treatment is a type of treatment used to manage or relieve sudden worsening of symptoms when the regular treatment isn't enough to control the problem. It is an add-on medication, not a replacement to current treatment.

Proteinuria reduction at 9 months*



Average UPCR (g/g)*	FABHALTA	Placebo
Start of study	1.9 g/g (n=125)	2.0 g/g (n=125)
Month 9	1.0 g/g (n=119)	1.7 g/g (n=110)

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.

Please see additional Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

SAFETY PROFILE OF FABHALTA IN THE CLINICAL TRIAL

Adverse reactions reported in ≥3% of adult patients with IgAN treated with FABHALTA and ≥2% higher in frequency than placebo (sugar pill) in the clinical trial.*

ADVERSE REACTION	FABHALTA (N = 235) n (%)	Placebo (N = 235) n (%)
Upper respiratory tract infection	20 (9)	16 (7)
Lipid disorder†	15 (6)	10 (4)
Abdominal pain†	15 (6)	5 (2)
Nausea	8 (3)	2 (1)
Dizziness	7 (3)	2 (1)

*The median time of exposure for FABHALTA was 43 weeks.

†Includes similar terms.

- **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.

REMS

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

See pages 9 and 10 for more information on the risk of serious infection and the need for vaccinations.

See page 11 for more on the FABHALTA REMS program.

The data on this page reflect patients with IgAN (eGFR ≥20 mL/min/1.73 m^2 at baseline) who received FABHALTA (N=235) or placebo (sugar pill) (N=235) treatment as of the time of the efficacy analysis.

eGFR, estimated glomerular filtration rate.

Please see Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Patient portrayal.

"It's just a part of me, it's not all of me. That's my mantra–[IgAN] doesn't define me, only I can define me."

— Real IgAN patient

VACCINATIONS NEEDED 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.

Certain vaccinations help protect you from the risk of serious infections while you are taking FABHALTA.

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 you have completed your required vaccinations and 2 weeks have passed,* you can begin FABHALTA right away.

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.

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

For more information about vaccination requirements, tips, and a vaccination checklist, please visit www.fabhalta.com/igan/getting-started.

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 a stiff neck or stiff back
- Body aches with flu-like symptoms
- Eyes sensitive to light

Please see Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

IF YOU HAVE NOT COMPLETED YOUR REQUIRED VACCINATIONS, YOU HAVE 2 OPTIONS

OPTION 1

If you have not completed or updated your vaccinations before starting FABHALTA:

1. Complete or update your required vaccinations
2. Wait at least 2 weeks
3. Begin treatment with FABHALTA

OPTION 2

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.

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 of the possible side effects of FABHALTA.
Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How can I get help obtaining my vaccinations?

Your care team is your best source of information. Still have questions? Novartis Patient Support (NPS) can help you locate vaccination centers and offer other assistance along the way. For more on NPS, see page 16.

Please see Important Safety Information throughout and on pages 12-14, 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 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, as discussed above

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 between 8:00 AM and 4:00 PM ET or visit **Fabhalta-REMS.com** today.

FABHALTA® (iptacopan) 200 mg capsules

Please see Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

APPROVED USE AND IMPORTANT SAFETY INFORMATION FOR FABHALTA (iptacopan)

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 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

ADDITIONAL IMPORTANT SAFETY INFORMATION >>

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

FABHALTA® (iptacopan) 200 mg capsules

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

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.

ADDITIONAL IMPORTANT SAFETY INFORMATION >>

Please see additional Important Safety Information throughout and on pages 12 and 14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

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

The most common side effects of FABHALTA in adults include:

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

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

Call your doctor for medical advice about side effects.
You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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

FABHALTA CAN FIT INTO YOUR DAILY ROUTINE

One capsule. Twice a day.

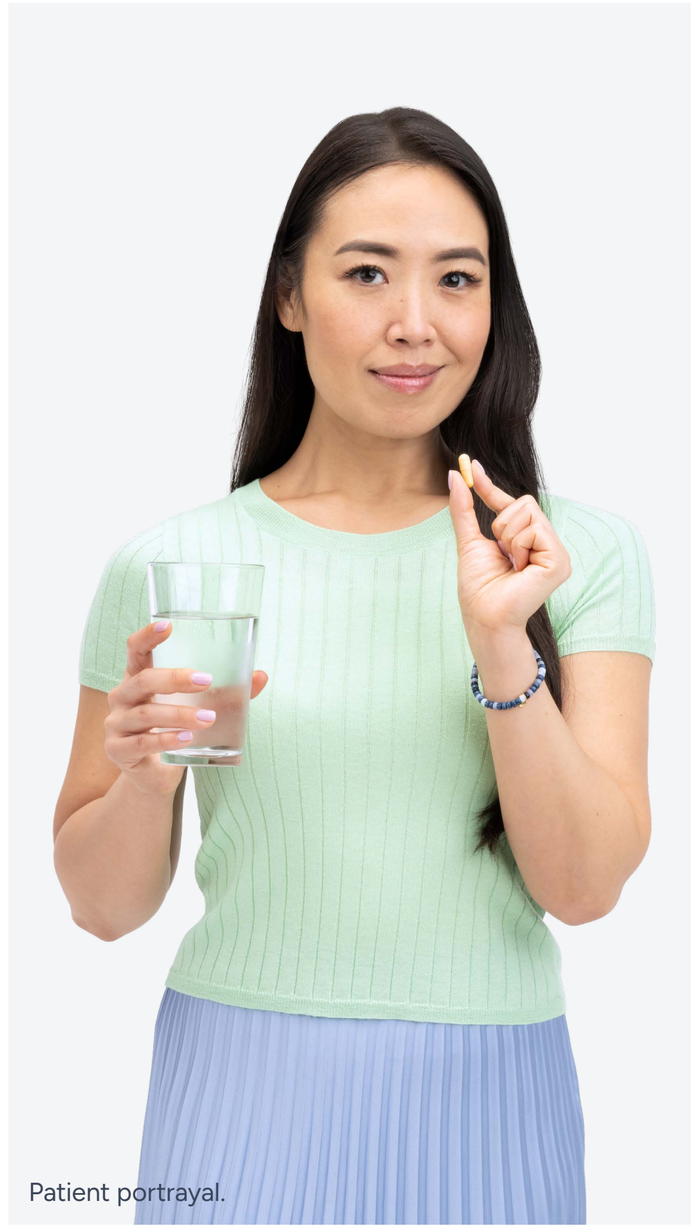
- Each capsule contains 200 mg of FABHALTA
- Take one capsule twice a day with or without food
- Swallow the capsules whole
- **Do not** open, break, or chew capsules

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

DID YOU KNOW?	***FABHALTA is not a steroid. Ask your health care provider how FABHALTA can help reduce proteinuria.***



Patient portrayal.

Important Safety Information (continued)

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

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

- Enroll in the FABHALTA REMS program.
- Counsel you about the risk of serious infections caused by certain bacteria.
- Give you information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that you receive antibiotics if you need to start FABHALTA right away and you are not up to date on your vaccinations.
- Give you a **Patient Safety Card** about your risk of serious infections.

Please see additional Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

NOVARTIS PATIENT SUPPORT CAN HELP YOU EVERY STEP OF THE WAY

Personalized assistance that can help you start, stay, and save on treatment

Once you and your health care provider decide to begin FABHALTA, you can sign up or designate a loved one to sign you up for Novartis Patient Support. It's a personalized program that may help you start, stay, and save on treatment.

Now, you have a dedicated team in your corner to help with:

Navigating the Insurance Process

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

Vaccination Support

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

Financial Support

Your dedicated Novartis Patient Support team will work with you to help identify financial support options.

Ongoing Support

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

Sign up for Novartis Patient Support

There are a few different ways to start getting support:

1. **Call 1-833-99FABHA (1-833-993-2242)**, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays. Your dedicated Novartis Patient Support team can then help you sign up
2. Sign up online by visiting **support.FABHALTA.com**
3. **Ask your health care provider** to help sign you up at your next appointment

FINANCIAL SUPPORT

Learn about the $0 Co-Pay Plus* offer and FABHALTA Bridge Program† on the next page. Also see terms and conditions indicated with footnote symbols on the next page.

Please see Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

NOVARTIS PATIENT SUPPORT TERMS AND CONDITIONS

Novartis Patient Support™

$0 Co-Pay Plus offer*

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

FABHALTA Bridge Program†

If you have private or commercial insurance, 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 the Co-Pay Plus* Program, scan the QR code or call 1-833-99FABHA (1-833-993-2242).

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

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

FABHALTA® (iptacopan) 200 mg capsules

Please see Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

TAKE THE NEXT STEP IN YOUR IgAN JOURNEY

FABHALTA® (iptacopan) 200 mg capsules

Primary Study Objective

In a clinical study* of adult patients with primary IgAN at risk of disease worsening quickly

FABHALTA substantially reduced proteinuria at 9 months compared to placebo (sugar pill)

44% vs **9%**

reduction in proteinuria with FABHALTA (119 of 125 people)

with placebo (110 of 125 people)

Average UPCR (g/g) at Baseline*	1.9 g/g	2.0 g/g
Average UPCR (g/g) at Month 9*	1.0 g/g	1.7 g/g

- The most common adverse reactions in adults with IgAN (≥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)
- Because of the risk of serious infections, FABHALTA is only available through a REMS program that requires vaccinations
  - See pages 9 and 10 for more information on vaccinations. See page 11 for more on the FABHALTA REMS program

*This is a phase 3, placebo-controlled clinical study of adult patients with biopsy-proven IgAN. Efficacy results were analyzed in the first 250 patients with eGFR ≥30 mL/min/1.73 m^2. 125 participants taking 200 mg of FABHALTA twice daily were compared with 125 participants taking a placebo control (sugar pill) twice daily. All participants had elevated proteinuria (UPCR ≥1 g/g) at the start of the study and were receiving a stable dose of maximally tolerated blood pressure medications (ACEi/ARB) with or without other background therapies before and throughout the study. In the efficacy analysis, there were 125 patients in each arm at Baseline and at Month 9 there were 119 and 110 in the FABHALTA and placebo arms, respectively.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; REMS, risk evaluation and mitigation strategy; UPCR, urine protein-to-creatinine ratio.

FABHALTA is not a steroid. Ask your health care provider if FABHALTA could be right for you.

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.

Please see additional Important Safety Information throughout and on pages 12-14, and full Prescribing Information, including Boxed WARNING and Medication Guide.

Important Safety Information

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

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

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria**, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life threatening or fatal if not recognized and treated early.

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