

UNDERSTANDING YOUR IgAN

Use this resource to learn more about your immunoglobulin A nephropathy (IgAN) and define some of the unfamiliar terms you might come across.

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 10 and 11. Please see full [Prescribing Information](#), including Boxed WARNING and [Medication Guide](#).



Doctor and patient portrayal.



FABHALTA
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NAVIGATING THIS RESOURCE

To help you feel more confident along your journey, we've broken down how IgAN (immunoglobulin A nephropathy) impacts your body and explained some of the common terms you might hear.

Some of the topics we cover include:

- The role of your kidneys ([See page 3](#))
- The immune system and your kidneys ([See page 3](#))
- How IgAN impacts your kidneys ([See page 4](#))
- A different approach to treatment ([See page 5](#))
- Common IgAN terms ([See page 6](#))
- Support team terms ([See page 8](#))
- Insurance coverage terms ([See page 9](#))

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Patient portrayal.



Not sure about something? Speak up.

If you have questions about IgAN, be sure to write them down and bring them up at your next appointment.

Your doctors are always your best source of information.

Important Safety Information (continued)

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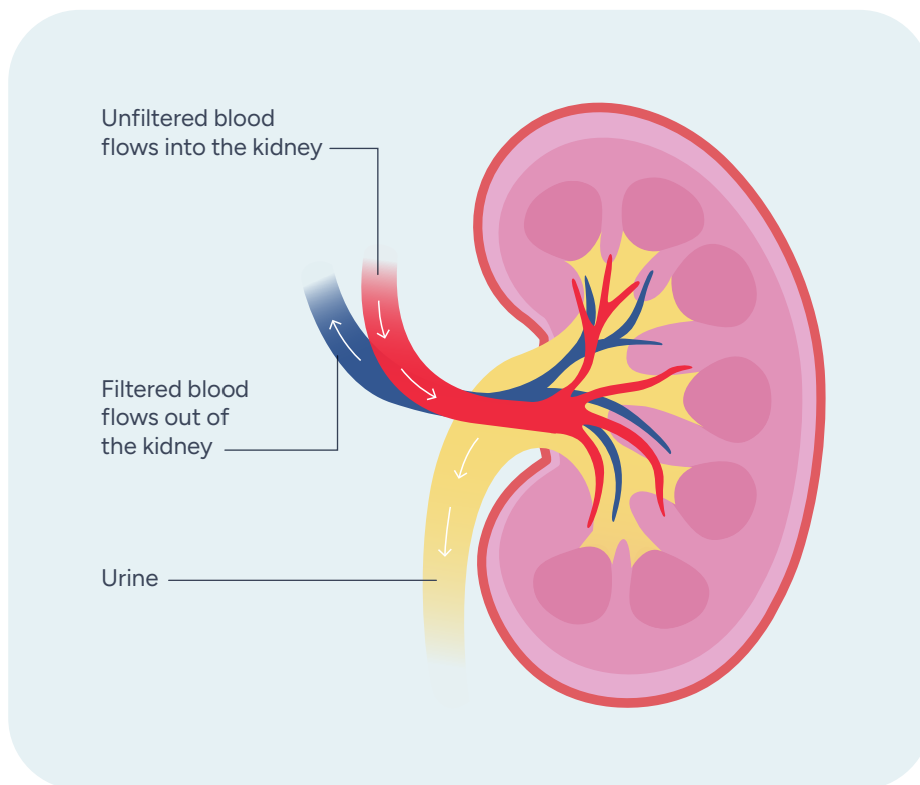
THE ROLE OF YOUR KIDNEYS

Your kidneys perform many complex and vital functions that keep the rest of the body in balance.

The main function of your kidneys is to filter your blood. **They remove waste and extra water, making urine, and return cleaned blood back to your body.**

Other important functions of your kidneys include:

- **Maintaining a healthy balance of water, salts, and minerals**
- **Controlling your blood pressure**
- **Stimulate the making of red blood cells**
- **Keeping your bones strong and healthy**



Your kidneys and your immune system work as a team and depend on each other to stay healthy.

By filtering toxins, the kidneys help balance vital functions of the immune system. At the same time, your immune system protects your kidneys from foreign elements that could disrupt their function and can play a role in certain kidney diseases, like IgAN.

Important Safety Information (continued)

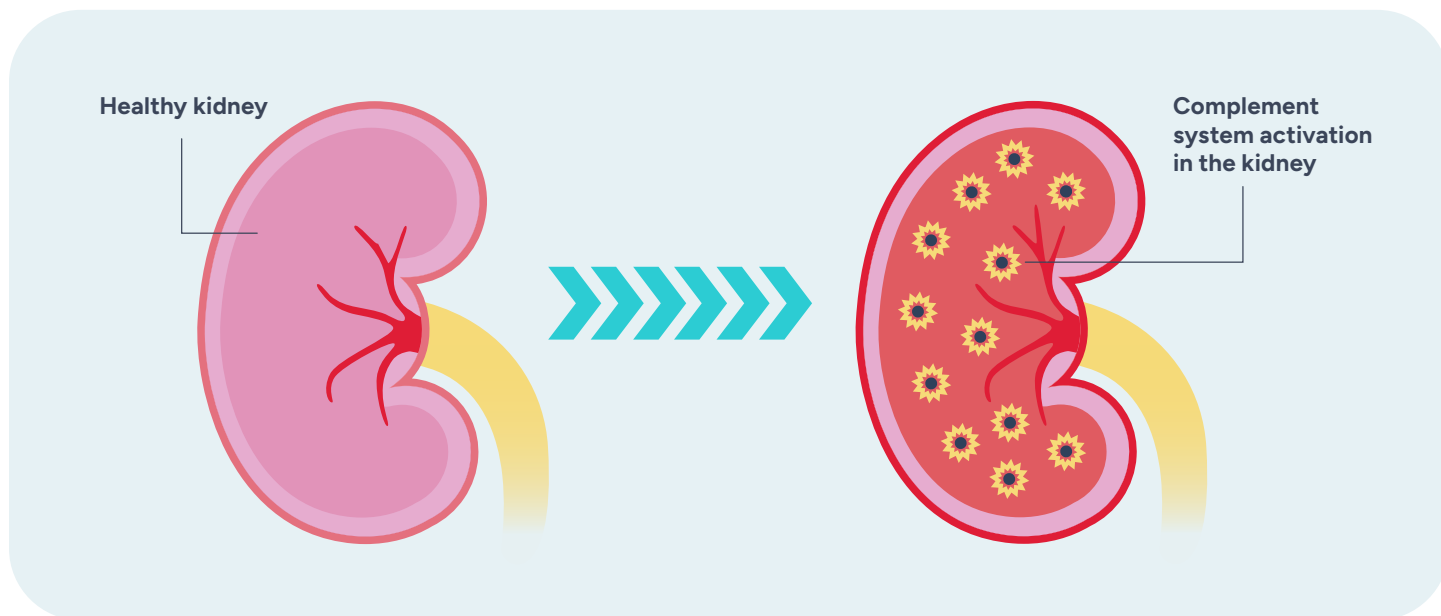
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HOW IgAN IMPACTS YOUR KIDNEYS



- 1 IgAN occurs when IgA antibodies that are supposed to fight infections become defective and cause your immune system to work against itself.
- 2 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.
- 3 Activation of multiple pathways, including the complement system, may result in inflammation, kidney injury, and scarring.

See page 6 for a further definition of the complement system.

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

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TAKE A DIFFERENT APPROACH WITH FABHALTA®

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.

You may have tried other treatment options or considered steroids, but FABHALTA works differently, and worsening lab numbers could signal it's time for a change.

FABHALTA helps block a part of the complement system.



FABHALTA

Learn more about FABHALTA. [Click here.](#)



Patient portrayal.

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 - Fever with or without shivers or chills
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COMMON IgAN TERMS

Antibodies

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

Asymptomatic

When you show no symptoms of disease. Without showing symptoms, it can be difficult to get a diagnosis.

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.

CKD

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

Complement System

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

eGFR

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

ESKD/ESRD

End-stage kidney disease (ESKD), also called end-stage renal disease (ESRD). This is the last stage of chronic kidney disease, when your kidneys can no longer filter your blood. If this occurs, external blood filtering (dialysis) treatment is required.

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).

Immunodeficiency

When your immune system cannot adequately protect your body from infection.

Immunoglobulin A (IgA)

Immunoglobulin A (IgA) 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.

Pathway

A series of actions among molecules for sending and receiving signals, which leads to certain reactions and functions in your body.

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.

Urine Protein-to-Creatinine Ratio (UPCR):

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

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TERMS RELATING TO IgAN TREATMENT

ACEi/ARB

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

Biopsy

A medical procedure that uses cells, tissue, or fluid from your body to diagnose a medical condition or to check whether a treatment is working.

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.

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.

Kidney Transplant

Surgically implanting a kidney from a living or deceased donor into a person with kidney failure or ESKD.

MEST-C

A measurement of changes in kidney tissue. The MEST-C score is used to predict how fast kidney function will decline.

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.
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COMMON SUPPORT TEAM TERMS

Pathologist

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

Nephrologist

A doctor who diagnoses and treats kidney conditions and diseases.

Physician Assistant (PA)

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

Nurse Practitioner (NP)

A nurse with advanced training who can perform physical exams, diagnose and treat diseases, and prescribe medications. NPs have more education and training than regular nurses and can administer certain types of care independently of medical doctors.

Patient Navigator

A professional who helps guide patients through the screening, diagnosis, and treatment of a medical condition by providing practical help and advice. Duties include setting up appointments, communicating with doctors and health care providers, and helping patients find financial, legal, or social assistance.

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 be certified in the FABHALTA REMS program, so that they may prescribe you FABHALTA. You do not have to enroll in anything yourself.

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.

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

- Have an infection or fever.
- Have liver problems.
- Are pregnant or plan to become pregnant. It is not known if FABHALTA will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if FABHALTA passes into your breast milk. You should not breastfeed during treatment and for 5 days after your final dose of FABHALTA.

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COMMON INSURANCE COVERAGE TERMS

Appeal

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

Bridge Program

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

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.

Co-Insurance

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 co-insurance, your insurance plan covers 100% of the cost.

Patient Support Program

A program that helps patients, caregivers, and health care professionals find the right 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.

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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 | • Pain in the stomach (abdomen) |
| • Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis) | • Infections (bacterial and viral) |
| • Diarrhea | • 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.

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STAY INFORMED

Armed with the information you need to move forward?

More than just knowing the facts, remember to communicate with your care team about how you're feeling.

Use the **FABHALTA Doctor Discussion Guide** to prepare for your next appointment, and take charge of your IgAN care plan with a confident step forward.



HAVING A PRODUCTIVE CONVERSATION WITH YOUR DOCTOR

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

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