



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

# GETTING STARTED ON FABHALTA: VACCINATION GUIDE

**Important vaccination information before  
starting FABHALTA**

Patient portrayal.



**Learn about the option for  
in-home vaccinations on page 6**



## Approved Uses

### What is FABHALTA?

FABHALTA is a prescription medicine used to:

- Treat adults with paroxysmal nocturnal hemoglobinuria (PNH).
- Reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly.

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.

- Treat adults with a kidney disease called complement 3 glomerulopathy (C3G), to reduce protein in the urine (proteinuria).

It is not known if FABHALTA is safe and effective in children with PNH, IgAN, or C3G.

**Please see additional Important Safety Information throughout and on pages 7-9 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.

# READY TO START FABHALTA?

**You must complete or update certain vaccinations at least 2 weeks before starting FABHALTA.**

This guide, along with Novartis Patient Support™ (NPS) and your care team, can help you navigate the vaccination process.



**This quick guide can help you understand:**

**WHY** you need certain vaccinations



**WHAT** vaccinations you need



**WHEN** you need to get your vaccinations



**HOW** NPS and your care team can help



## 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 [7-9](#) and full [Prescribing Information](#), including **Boxed WARNING** and [Medication Guide](#).

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# WHY

## YOU NEED CERTAIN VACCINATIONS

***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 fatal if not recognized and treated early.



Doctor and patient portrayal.

**Keep reading to learn about the vaccinations you need before starting FABHALTA.**



### ***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.

**Please see additional Important Safety Information throughout and on pages 7-9 and full Prescribing Information, including Boxed WARNING and Medication Guide.**



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# WHAT

# VACCINATIONS YOU NEED

You must complete or update the following vaccinations at least 2 weeks before your first dose of FABHALTA:

VACCINE	PURPOSE
<b>Pneumococcal</b>	Helps protect you from the risk of pneumonia caused by <i>Streptococcus pneumoniae</i> infection
<b>Meningococcal</b>	Helps protect you from the risk of meningitis caused by <i>Neisseria meningitidis</i> infection

Several types of pneumococcal and meningococcal vaccines are available. You may have received some of these vaccines in the past. Your health care provider will inform you of the vaccinations and number of doses you need based on your age and vaccination history.

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

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 high heart rate
- Fever and rash
- Headache with stiff neck or stiff back
- Fever with chest pain and cough
- Headache and fever
- Fever with breathlessness or fast breathing
- Body aches with flu-like symptoms
- Confusion
- Headache with nausea or vomiting
- Eyes sensitive to light
- Clammy skin

## Important Safety Information (continued)

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

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

Please see additional Important Safety Information throughout and on pages 7-9 and full Prescribing Information, including Boxed WARNING and Medication Guide.

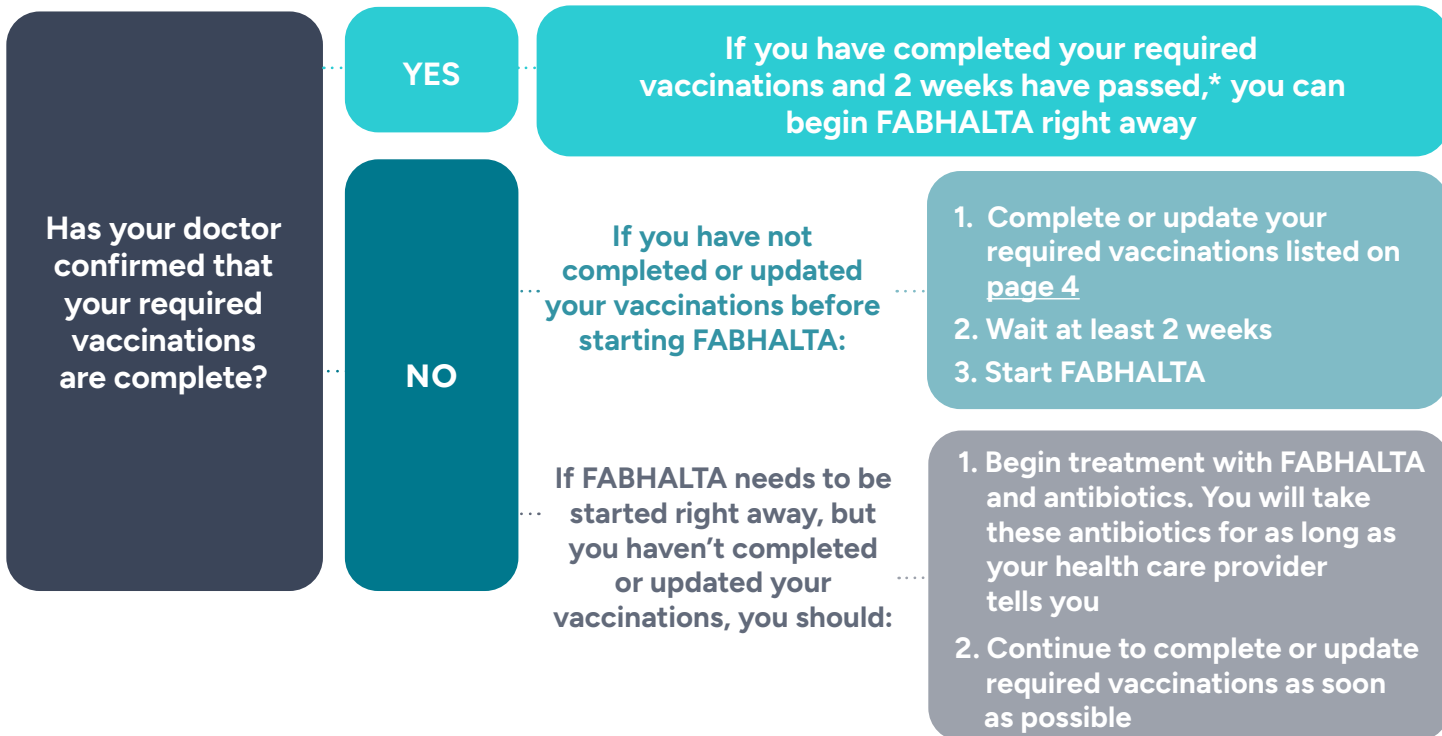
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# WHEN

# YOU NEED TO GET YOUR VACCINATIONS

**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:



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.

**Keep reading to learn how to get the vaccines you need before starting FABHALTA.**



## Important Safety Information (continued)

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

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or fatal if not recognized and treated early.
  - If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.

**Please see additional Important Safety Information throughout and on pages 7-9 and full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).**



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# HOW

## NPS AND YOUR CARE TEAM CAN HELP

### ***NPS is here to help you begin your treatment with FABHALTA***

Our Vaccination Support program provides in-home vaccination and guided navigation to help simplify the process for eligible patients, regardless of insurance.

#### **Vaccination Support consists of:**



**In-home vaccination**—a licensed clinician administering all required vaccinations in your home at no cost



**Guidance throughout the vaccination process**—helps you navigate the steps needed to receive the required vaccinations, including finding a vaccination location near you

We can also offer patients guidance on accessing existing vaccination records.

**Download Vaccination Tips**



**Download Vaccination Card**



Eligible patients can use their **Co-Pay Plus\*** offer to help lower their out-of-pocket costs to **as little as \$0** for the required vaccination(s), up to \$1,000 annually, excluding administration costs.

**To sign up for NPS, simply [click here](#) or call [833-99FABHA](#) (833-993-2242).**

\*Limitations apply. Up to a \$20,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at [www.fabhalta.com](http://www.fabhalta.com) for details.

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# APPROVED USES AND IMPORTANT SAFETY INFORMATION FOR FABHALTA® (iptacopan)

## Approved Uses

### What is FABHALTA?

FABHALTA is a prescription medicine used to:

- Treat adults with paroxysmal nocturnal hemoglobinuria (PNH).
- Reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at risk of their disease progressing quickly.

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.

- Treat adults with a kidney disease called complement 3 glomerulopathy (C3G), to reduce protein in the urine (proteinuria).

It is not known if FABHALTA is safe and effective in children with PNH, IgAN, or C3G.

## Important Safety Information

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

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

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria**, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or fatal if not recognized and treated early.
  - You must complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of FABHALTA.
  - If you have not completed your vaccinations and FABHALTA must be started right away, you should receive the required vaccinations as soon as possible.

- If you have not been vaccinated and FABHALTA must be started right away, you should also receive antibiotics to take for as long as your health care provider tells you.
- If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.

- Vaccines do not prevent all infections caused by encapsulated bacteria.

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

- |   |   |
|---|---|
| ▪ Fever with or without shivers or chills | ▪ Fever with breathlessness or fast breathing |
| ▪ Fever with chest pain and cough         | ▪ Headache with nausea or vomiting            |
| ▪ Fever with high heart rate              | ▪ Headache with stiff neck or stiff back      |
| ▪ Headache and fever                      | ▪ Body aches with flu-like symptoms           |
| ▪ Confusion                               | ▪ Eyes sensitive to light                     |
| ▪ Clammy skin                             |   |
| ▪ Fever and rash                          |   |

**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.

**IMPORTANT SAFETY INFORMATION CONTINUES >>**

**Please see additional Important Safety Information throughout and on pages 8-9 and full Prescribing Information, including Boxed WARNING and Medication Guide.**

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# APPROVED USES AND IMPORTANT SAFETY INFORMATION FOR FABHALTA® (iptacopan)

## (CONTINUED)

### 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.

#### 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.

#### For people with PNH:

- **If you stop taking FABHALTA**, your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. **Stopping FABHALTA may cause a breakdown of red blood cells due to PNH.**

##### Symptoms or problems that can happen due to breakdown of red blood cells include:

- Decreased hemoglobin level in your blood
  - Tiredness
  - Pain in the stomach (abdomen)
  - Blood in your urine
  - Blood clots, stroke, and heart attack
  - Shortness of breath
  - Erectile dysfunction
  - Trouble swallowing
- It is important you take FABHALTA exactly as your health care provider tells you to lower the possibility of breakdown of red blood cells due to PNH.

IMPORTANT SAFETY INFORMATION CONTINUES >>

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# APPROVED USES AND IMPORTANT SAFETY INFORMATION FOR FABHALTA® (iptacopan) (CONTINUED)

## 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.

### The most common side effects of FABHALTA in adults include:

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

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

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

**Please see additional Important Safety Information throughout and on pages 7-8 and full Prescribing Information, including Boxed WARNING and Medication Guide.**

# FABHALTA VACCINATION OVERVIEW

## 3 important steps to completing or updating your required vaccinations before getting started with FABHALTA:



**Ask your health care provider** about the specific vaccinations you need before starting FABHALTA



**Complete or update your vaccinations** against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of FABHALTA



Partner with NPS to **locate the closest vaccination center to you** or arrange for **in-home vaccine administration**

**See the “Getting Started & Vaccinations” page at [www.FABHALTA.com](http://www.FABHALTA.com) for more information.**

[www.FABHALTA.com](http://www.FABHALTA.com)



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