

MEDICATION GUIDE
FABHALTA® (fab hal tah)
(iptacopan)
capsules, for oral use

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

FABHALTA is a medicine that affects part of your immune system. FABHALTA may lower the ability of your immune system 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 healthcare provider tells you.
 - If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your healthcare provider will decide if you need additional vaccinations.
 - Vaccines do not prevent all infections caused by encapsulated bacteria. **Call your healthcare provider or get emergency medical care right away if you have any of these signs and symptoms of a serious infection:**
 - fever with or without shivers or chills
 - fever with chest pain and cough
 - fever with high heart rate
 - headache and fever
 - confusion
 - clammy skin
 - fever and a rash
 - fever with breathlessness or fast breathing
 - headache with nausea or vomiting
 - headache with stiff neck or stiff back
 - body aches with flu-like symptoms
 - eyes sensitive to light

Your healthcare 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 healthcare 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 healthcare 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

For more information about side effects, see **“What are the possible side effects of FABHALTA?”**

What is FABHALTA?

FABHALTA is a prescription medicine used to:

- treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH).
- reduce levels of 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.
- treat adults with a kidney disease called complement 3 glomerulopathy (C3G), to reduce levels of protein in the urine (proteinuria).

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

Who should not take FABHALTA?

Do not take FABHALTA if you:

- are allergic to iptacopan or any of the ingredients in FABHALTA. See the end of this Medication Guide for a complete list of 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 treatment.

Before you take FABHALTA, tell your healthcare provider about all of 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 healthcare 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 healthcare provider and pharmacist when you get a new medicine.

How should I take FABHALTA?

- Take FABHALTA exactly as your healthcare provider tells you. Do not change the dose or stop taking FABHALTA unless your healthcare provider tells you.
- Take 1 FABHALTA capsule 2 times each day, with or without food.
- Swallow the capsules whole. **Do not** open, break, or chew capsules.
- If you miss a dose or doses of FABHALTA, take 1 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 of FABHALTA at your regularly scheduled time.

For people with PNH:

- **If you are changing treatment from eculizumab to FABHALTA**, you should take your starting dose of FABHALTA no later than 1 week after your last dose of eculizumab.
- **If you are changing treatment from ravulizumab to FABHALTA**, you should take your starting dose of FABHALTA no later than 6 weeks after your last dose of ravulizumab.
- **If you stop taking FABHALTA**, your healthcare provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. **Stopping treatment with 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
- blood in your urine
- pain in the stomach (abdomen)
- shortness of breath
- blood clots, stroke, and heart attack
- trouble swallowing
- erectile dysfunction
- It is important you take FABHALTA exactly as your healthcare provider tells you to lower the possibility of breakdown of red blood cells due to PNH.

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 healthcare provider will do blood tests to check your cholesterol and triglycerides during treatment with FABHALTA. Your healthcare 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 healthcare provider about any side effect that bothers you or that does not go away. These are not all of the possible side effects of FABHALTA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FABHALTA?

- Store FABHALTA capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- The FABHALTA container contains a child resistant cap.

Keep FABHALTA and all medicines out of the reach of children.

General information about the safe and effective use of FABHALTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FABHALTA for a condition for which it was not prescribed. Do not give FABHALTA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about FABHALTA that is written for health professionals.

What are the ingredients in FABHALTA?

Active ingredient: iptacopan

Inactive ingredients: the capsule shell contains gelatin, red ferric oxide, titanium dioxide, yellow ferric oxide. The black printing ink contains ferrousferrous oxide, potassium hydroxide, propylene glycol, shellac, and strong ammonia solution.

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For more information, go to www.FABHALTA.com or call 1-888-669-6682.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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