



PATIENT & CAREGIVER EDUCATION

Iptacopan

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Fabhalta

Brand Names: Canada

Fabhalta

Warning

- This drug raises the risk of severe infections, especially meningococcal, *Haemophilus influenzae*, and *Streptococcus pneumoniae* infections. Life-threatening and deadly infections have happened in people treated with this type of drug. These types of infections can become life-threatening or deadly very fast if not treated early. Vaccines can help lower the risk of these infections. You will need to get certain vaccines at least 2 weeks before starting this drug unless your doctor tells you otherwise. Even if you have had these vaccines before, you may need to get another one.
- Vaccines lower the risk of infections but do not prevent all infections from happening. Call your doctor right away if you have signs of a severe infection like fever with or without a rash, fast heartbeat, chills, chest pain, trouble breathing, or cough; headache with upset stomach or throwing up, fever, or stiff neck or back; confusion; clammy skin; body aches with flu-like signs; or if light bothers your eyes.

What is this drug used for?

- It is used to treat a blood disease called paroxysmal nocturnal hemoglobinuria (PNH).
- It is used to lower protein in the urine in patients with a certain kidney problem (immunoglobulin A nephropathy, IgAN).
- It is used to treat a kidney problem called complement 3 glomerulopathy (C3G).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

- If you have a meningococcal, *Haemophilus influenzae*, or *Streptococcus pneumoniae* infection.
- If you have not had a vaccine against meningococcal or *Streptococcus pneumoniae* infection.
- If you have any of these health problems: Kidney disease or liver disease.
- If you are taking gemfibrozil.
- If you are breast-feeding. Do not breast-feed while you take this drug and for 5 days after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you cannot get the needed vaccines at least 2 weeks before starting this drug, you will need to take antibiotics as your doctor tells you.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Have your patient safety card with you at all times and for 2 weeks after your last dose.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- High cholesterol and triglyceride levels have happened with this drug. If you have high cholesterol or triglycerides, talk with your doctor.

- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of a common cold.
- Any unexplained bruising or bleeding.
- Patients who take this drug for PNH may have some health problems after they stop taking it. If you have PNH, you will need to be watched closely for at least 2 weeks after stopping this drug. Call your doctor right away if you have dark urine; swelling, warmth, or pain in the leg or arm; chest pain or pressure; coughing up blood; trouble breathing or swallowing; or stomach pain. Call your doctor right away if you feel confused, very tired or weak, or have weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on 1 side of the face, or change in eyesight. Call your doctor right away if you are not able to get or keep an erection.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness or headache.
- Nose or throat irritation.
- Stomach pain or diarrhea.
- Upset stomach.
- Joint pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Swallow whole. Do not chew, open, or break.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it even if it is close to your next dose. After taking a missed dose, take your next dose at the normal time.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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