

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **FABHALTA**[®]

iptacopan capsules

This Patient Medication Information is written for the person who will be taking **FABHALTA**[®]. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **FABHALTA**, talk to a healthcare professional.

Serious warnings and precautions box

FABHALTA may increase your risk of infections caused by certain types of bacteria. This includes *Streptococcus pneumoniae* and *Neisseria meningitidis*.

- Talk to your healthcare professional before you start FABHALTA to be sure that you receive the required vaccinations. Even if you have had these vaccinations in the past, you might still need a booster (additional vaccinations) before starting this medicine.
- You should be given these vaccinations at least 2 weeks before starting FABHALTA. If this is not possible, you will be vaccinated as soon as possible after you start FABHALTA and your healthcare professional will prescribe antibiotics. You should take your antibiotics until 2 weeks after you have been vaccinated to reduce the risk of infection.
- Vaccines reduce the risk of serious infections but may not prevent all serious infections. You should be closely monitored by your healthcare professional for symptoms of infection and you should inform them right away if you have any signs of a serious infection during treatment with FABHALTA, such as:
 - fever with or without shivers or chills
 - fever and a rash
 - fever with chest pain and cough
 - fever with breathlessness/fast breathing
 - fever with high heart rate
 - headache with nausea or vomiting
 - headache and a fever
 - headache with stiff neck or stiff back
 - confusion
 - body aches with flu-like symptoms
 - clammy skin
 - eyes sensitive to light

FABHALTA is only available through a controlled distribution program. Your healthcare professional will enroll you in this program and counsel you on the risk of serious infections. They will also give you a patient guide and patient card. Talk to your healthcare professional if you have any questions about this program.

What FABHALTA is used for:

FABHALTA is used to treat adults with:

- Paroxysmal Nocturnal Hemoglobinuria (PNH), who have low levels of red blood cells due to the breakdown of the red blood cells. PNH is a type of disease that affects the blood system.
- Complement 3 Glomerulopathy (C3G) to reduce levels of protein in the urine (proteinuria). C3G is a type of kidney disease caused by your body's immune system.

How FABHALTA works:

FABHALTA belongs to a class of medicines called selective immunosuppressants.

- In patients with PNH, a group of proteins in the immune system called “complement system” is overactive and attacks the red blood cells. FABHALTA works by attaching to a protein called Factor B and blocks the complement system from attacking red blood cells. This helps to increase the number of red blood cells (reduce anemia) and control PNH.
- In patients with C3G, the complement system is overactive, leading to a buildup of C3 protein within the glomeruli (a part of the kidneys) causing inflammation and damage. This often causes high levels of protein in the urine (proteinuria) and a gradual decline in kidney function over time. By attaching to the Factor B protein, FABHALTA reduces the buildup of C3 protein in the kidneys. This helps to reduce protein levels in the urine and may stabilize kidney function.

The ingredients in FABHALTA are:

Medicinal ingredient: iptacopan (as iptacopan hydrochloride monohydrate)

Non-medicinal ingredients: Black iron oxide, concentrated ammonia solution, gelatin, potassium hydroxide, propylene glycol, red iron oxide, shellac, titanium dioxide, yellow iron oxide

FABHALTA comes in the following dosage form

Capsules: 200 mg

Do not use FABHALTA if:

- you are allergic (hypersensitive) to iptacopan or any of the other ingredients of FABHALTA
- you are not vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae* unless your healthcare professional decides that urgent treatment with FABHALTA is needed.
- you have a serious infection caused by encapsulated bacteria including *Neisseria meningitidis*, *Streptococcus pneumoniae*, or *Haemophilus influenzae* type B, prior to starting FABHALTA treatment.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FABHALTA. Talk about any health conditions or problems you may have, including if you:

- have an infection.
- have liver problems.

Other warnings you should know about:

- **Children and adolescents (*less than 18 years of age*)**
 - You should not take FABHALTA if you are below 18 years of age. No data are available on the safety and effectiveness of FABHALTA in this age group.
- **Pregnancy and breast-feeding**
 - If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before taking this medicine.
 - Your healthcare professional will discuss with you the potential risks of taking FABHALTA during pregnancy or breast-feeding.

You should also tell your healthcare professional if you become pregnant during the treatment with FABHALTA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FABHALTA:

- Rifampin, used to treat bacterial infections
- Gemfibrozil, used to treat high triglycerides
- Carbamazepine, used to treat epilepsy

How to take FABHALTA:

- Always take FABHALTA exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.
- Swallow the FABHALTA capsule with a glass of water. Ideally once in the morning and once in the evening. Taking FABHALTA at the same time each day will help you to remember when to take your medicine.
- FABHALTA can be taken with or without food.

Usual dose:

The recommended dose is 200 mg twice daily.

If you have PNH and are switching from other PNH medicines to FABHALTA

- If you are switching from a medicine called **eculizumab**, you should start taking FABHALTA no later than one week after the last dose of eculizumab.
- If you are switching from a medicine called **ravulizumab**, you should start taking FABHALTA no later than 6 weeks after the last dose of ravulizumab.
- If you are switching from any other PNH medicine, ask your healthcare professional when to start taking FABHALTA.

How long to take FABHALTA

- PNH and C3G are lifelong conditions and it is expected that you will need to use FABHALTA for a long time. Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.
- If you have questions about how long you will need to take FABHALTA, talk to your healthcare professional.
- **Stopping your treatment with FABHALTA can make your condition worse. Do not stop taking FABHALTA without talking to your healthcare professional first.**
- If you have PNH:
 - your healthcare professional decides to stop your treatment with this medicine, they will monitor you closely for at least 2 weeks after stopping treatment for any signs of the breakdown of red blood cells (hemolysis) due to PNH. Your healthcare professional may prescribe a different PNH medicine or have you restart FABHALTA treatment.
 - Symptoms or problems that can happen due to breakdown of red blood cells include:
 - decrease in hemoglobin level in your blood
 - blood in the urine
 - shortness of breath
 - trouble swallowing
 - tiredness
 - pain in the stomach (abdomen)
 - blood clots (thrombosis)
 - erectile dysfunction

If you experience any of these after stopping treatment, contact your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much FABHALTA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose or doses of FABHALTA, take one dose as soon as you remember (even if it is soon before the next scheduled dose). Continue with your next scheduled dose at the usual time.

Possible side effects from using FABHALTA:

These are not all the possible side effects you may have when taking FABHALTA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with FABHALTA may include:

- Diarrhea
- Pain in the stomach (abdomen)
- Common cold (upper respiratory infection)
- Headache
- Nausea and vomiting (feeling sick)
- Joint pain (arthralgia)
- Hot flash

FABHALTA may cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Sepsis and septic shock (infection of the blood): fever, dizziness, chills, excessive sweating, high or very low body temperature, little or no urine, low blood pressure, rapid breathing, rapid heartbeat, confusion or decreased alertness			X
Pneumonia (infection in the lungs): chest pain when you breathe or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath			X
Unknown			
Fever		X	
Hemolysis (Breakdown of red blood cells): low blood counts (anemia), tiredness, difficulty in functioning, pain, dark urine, shortness of breath, and blood clots		X	
Chest discomfort			X
Ear infection		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store below 30°C
- Keep out of reach and sight of children.
- Do not take this medicine after the expiration date, which is stated on the box.

If you want more information about FABHALTA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca); or by calling 1-800-363-8883.

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