

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**PrFABHALTA®**

#### **Iptacopan capsules**

Read this carefully before you start taking **FABHALTA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FABHALTA**.

#### **Serious Warnings and Precautions:**

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 is FABHALTA 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.

### How does FABHALTA work?

In patients with PNH, a group of proteins in the immune system called “complement system” is overactive and attacks the red blood cells. FABHALTA belongs to a class of medicines called selective immunosuppressants. It 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.

### What are the ingredients in FABHALTA?

Medicinal ingredient: iptacopan (as iptacopan hydrochloride monohydrate)

Non-medicinal ingredients: Capsule shell: Gelatin, red iron oxide, titanium dioxide, yellow iron oxide

Printing ink: Black iron oxide, concentrated ammonia solution, potassium hydroxide, propylene glycol, shellac

### FABHALTA comes in the following dosage form:

Capsules: 200 mg

FABHALTA is available in packs containing 56 capsules (4 blisters of 14 capsules each).

### Do not use FABHALTA if:

- you are allergic (hypersensitive) to iptacopan or any of the other ingredients of FABHALTA (see **What are the ingredients in FABHALTA** above).
- 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 (18 years of age or younger)**
  - You should not take FABHALTA if you are 18 years of age or younger. 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, a medicine to treat bacterial infections
- Gemfibrozil, a medicine to treat high triglycerides
- Carbamazepine, a medicine 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.

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 is a lifelong condition 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 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, or regional poison control centre immediately, even if there are no 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.

**What are 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.

- 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			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN FREQUENCY</b>			
<b>Fever</b>		X	
<b>Hemolysis</b> (Breakdown of red blood cells): low blood counts (anemia), tiredness, difficulty in functioning, pain, dark urine, shortness of breath, and blood clots		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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health 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 this medicine out of the sight and reach 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 this Patient Medication Information by visiting the Health Canada 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](http://www.novartis.ca)) , by calling 1-800-363-8883, or by calling the FABHALTA patient support program at 1-877-580-5303.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised: JAN 06, 2025

FABHALTA is a registered trademark.