

A guide to treatment with **FABHALTA[®]** (iptacopan)

This guide is only intended for patients who have been prescribed FABHALTA[®] and their caregivers. This guide aims to provide you with important safety information for FABHALTA[®].

Please keep this document for future reference.

If you experience any side effects, talk to your doctor, nurse or pharmacist/other healthcare professional. This includes any possible side effects not listed in this guide.

If you have any questions or concerns about FABHALTA[®], speak with a healthcare professional.

Introduction

This guide has been developed to provide:

- Information about FABHALTA® and how it works
- Important safety information for FABHALTA®

If you have any questions or concerns about this medicine or your health and wellbeing, please speak with your treating physician, nurse or pharmacist/other healthcare professional.

Treating physician:

Nurse:

Pharmacist:



Your patient safety card

When you are first prescribed FABHALTA®, you are given a patient safety card.

This wallet-sized card contains important safety information about the risk of infection while taking FABHALTA®, and what to do if you get certain signs or symptoms.

It also contains the emergency contact details of your treating physician or hospital. The contact details will be added to the card by your treating physician.

Keep this card with you at all times during treatment, and for a period of 2 weeks following your last FABHALTA® dose, in case of an emergency. Show this card to any healthcare professional involved in your care so they know that you are being treated with FABHALTA®. This will help them to diagnose and treat you correctly.

If you have not received a patient safety card, please contact your treating physician or nurse.

What is in this guide?

p.4	About FABHALTA®
p.5	How do I take FABHALTA®?
p.6	What important safety risks do I need to know about?
p.7	Prophylactic vaccinations or antibiotic treatment
p.8	Risk of haemolysis after discontinuing FABHALTA®
p.9	How should I report side effects
p.10	Useful terms to know

About FABHALTA®



What is FABHALTA®?

FABHALTA® is used on its own in adults to treat paroxysmal nocturnal haemoglobinuria (PNH), a disease in which the immune system attacks and damages red blood cells, resulting low levels of red blood cells in the body (anaemia).

FABHALTA® contains the active substance iptacopan. It is designed to target the Factor B protein, which is part of the body's immune defence system called the "complement system". Iptacopan belongs to a group of medicines called complement inhibitors, which work by blocking specific parts of the complement system. This is how FABHALTA® prevents your body's immune system from destroying your red blood cells.



What happens in PNH?

The red blood cells are destroyed by your complement system in a process called haemolysis. Haemolysis causes low haemoglobin levels (anaemia), resulting in tiredness (fatigue), difficulty in functioning, pain, pain in the stomach (abdomen), dark urine, shortness of breath, difficulty swallowing, impotence and blood clots.



How does FABHALTA® work?

By attaching to and blocking the Factor B protein, FABHALTA® reduces activity of the complement system and can prevent red blood cells from being destroyed. This medicine helps to increase the number of red blood cells and thus may improve symptoms of anaemia.

How do I take FABHALTA®?

The recommended dose is one capsule (200 mg) twice daily, once in the morning and once in the evening. Swallow the capsule with a glass of water.

FABHALTA® can be taken with or without food.

It is important to not forget any dose. Taking FABHALTA® at the same time each day will help you remember to take your medicine. Please take FABHALTA® according to the schedule exactly as your treating physician tells you to lower the possibility of the breakdown of red blood cells in PNH (see page 8).

Do not stop taking FABHALTA® without talking to your treating physician first.

What if I forget to take FABHALTA®?

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

If you miss several doses in a row, contact your doctor who may decide to monitor you for any signs of the breakdown of red blood cells.

What if I take too much FABHALTA®?

If you have accidentally taken too many capsules or if someone else accidentally takes your medicine, talk to your treating physician or nurse immediately.

What important safety risks do I need to know about?

Risk of serious infections

FABHALTA® reduces your body’s defences against infection, specifically the activity of the complement system, which may increase the risk of certain serious infections.

This includes infections caused by specific types of bacteria called “encapsulated bacteria”. Examples of these are *Neisseria meningitidis*, *Streptococcus pneumoniae* and *Haemophilus influenzae* Type B.

Infections caused by these bacteria affect the nose, throat and lungs or the linings of the brain and can spread throughout the blood and body. Serious bacterial infections may quickly become life-threatening and cause death if not identified and treated early.

The signs and symptoms of serious infection you need to look out for are:

- **Fever**
 - With or without shivers or chills
 - With a headache
 - With a rash
 - With chest pain and cough
 - With breathlessness/ fast breathing
 - With high heart rate
- **Headache**
 - With feeling sick (nausea) or vomiting
 - With a stiff neck or stiff back
- **Confusion**
- **Body aches with flu-like symptoms**
- **Clammy skin**
- **Eyes sensitive to light**

Contact your treating physician in case you experience any of the signs and symptoms above and seek immediate medical care at the nearest hospital.

Carry your patient safety card with you and present it if the healthcare professional contacted is not the one involved in your PNH treatment.

Prophylactic vaccinations or antibiotic treatment



Vaccinations reduce the risk of certain serious bacterial infections.

Your treating physician will inform you about which vaccinations you need before starting treatment with FABHALTA®. You may need additional antibiotic treatment to prevent infection.

Vaccines you must be given are:

- Meningococcal vaccine
- Pneumococcal vaccine

Vaccine you may be given:

- *Haemophilus influenzae* Type B vaccine

These vaccines can protect you against serious diseases such as meningitis, pneumonia, and sepsis. Multiple different vaccinations are required to provide the most protection.

Even if you have had these vaccinations before, your treating physician will advise you on whether you need to have the same vaccination again or if you require booster vaccinations before starting treatment.

You must be given all of these vaccinations at least 2 weeks before you start treatment with FABHALTA®.


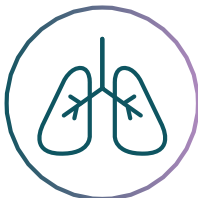



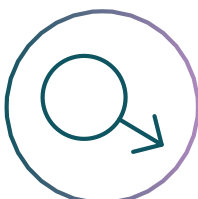

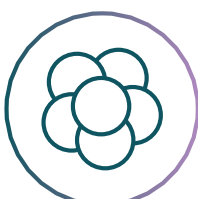
If your healthcare provider decides that treatment with FABHALTA® must be started right away and you have not completed your vaccinations, your doctor will prescribe antibiotics until 2 weeks after vaccination to help lower the chance of developing bacterial infections. You will only be supplied FABHALTA® if your doctor or pharmacist confirms that you are receiving the correct vaccinations or antibiotics.

To help prevent serious infections, it is important that your vaccines are up-to-date. Your doctor will make sure that you are revaccinated as needed. Please be aware, vaccinations reduce the chances of developing serious infections, but do not prevent them entirely. You will need to watch for signs and symptoms of serious infections even after receiving the vaccines.

Risk of haemolysis after discontinuing FABHALTA®

Discontinuing FABHALTA® may increase the risk of serious breakdown of red blood cells (haemolysis). It is important that you adhere to your prescribed treatment regimen.

The signs and symptoms of haemolysis you need to look out for are:

- | | | | |
|---|---|---|----------------------------------|
|  | Low levels of haemoglobin in your blood, as seen in blood tests |  | Shortness of breath |
|  | Tiredness |  | Trouble swallowing |
|  | Blood in the urine |  | Erectile dysfunction (impotence) |
|  | Pain in the stomach (abdomen) |  | Blood clots (thrombosis) |

Seek immediate medical attention if you notice any signs or symptoms of haemolysis.

If you want to stop taking FABHALTA®, talk to your treating physician before discontinuing treatment. If you miss a dose, take it as soon as you can, even if it is close to the next dose.

How should I report side effects?

Like all medicines, this medicine can cause side effects, although not everybody experiences them.

If you have any of the side effects listed in **this guide**, or any other side effects, including infections or serious haemolysis, report them immediately to a healthcare professional.

Useful terms to know

Anaemia

A low level of red blood cells in the blood. Anaemia is diagnosed by measuring the level of haemoglobin in the blood. Haemoglobin levels over 12 g/dL are considered normal for women, while over 13 g/dL are considered normal for men.

Complement inhibitors

Medicines that reduce the activity of the complement system, a part of the immune system.

Complement system

A part of the immune system that helps fight infection and remove damaged cells.

Haemoglobin

A protein in red blood cells that transports oxygen around the body.

Haemoglobinuria

High amounts of haemoglobin in the urine.

Haemolysis

Destruction of red blood cells.

Factor B

A protein that increases activity of the complement system.

Meningitis

A serious infection of the protective membranes that surround the brain and spinal cord (meninges), that causes a stiff neck, headache, and fever.

Paroxysmal nocturnal haemoglobinuria (PNH)

A rare and serious blood disorder in which red blood cells break apart more easily, leading to anaemia and other complications.

Pneumonia

A serious infection of one or both of the lungs.

Protein

Large molecules that have various roles in the body, including building and repairing tissues, enzymes, and hormones.

Red blood cells


Blood cells that carry oxygen from the lungs to the rest of the body.

Sepsis

An infection of the blood that causes the body's immune system to go into overdrive and can be life-threatening.

Thrombosis

When blood clots form in healthy blood vessels, which can block normal blood flow.



This booklet has been produced by Novartis (Singapore) Pte Ltd. The information provided is for educational purposes only and is not intended to replace discussions with your treating physician or care team.

FA-11212479 | Date of preparation: Aug 2025
This document has been approved by HSA as of 06-AUG-2025
FABHALTA® SG RMP Patient and Caregiver Guide version 1

Novartis (Singapore) Pte Ltd
20 Pasir Panjang Road, #10-25/28 Mapletree Business City, Singapore 117439
P +65 6722 6010 | F +65 6323 4335 | W www.novartis.com

