

A Patient and Caregivers guide to treatment with **FABHALTA® ▼ (IPTACOPAN)** for C3G & IgAN

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®.

This guide is not a replacement for the package leaflet you receive for this medicine – please keep this document for future reference.

▼ There is additional monitoring in place for FABHALTA® to help quickly identify new side effects. 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 or the leaflet you will find in the package.

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

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA



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 2 weeks after your last 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.

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About FABHALTA® for C3G

C3G

What is FABHALTA®?

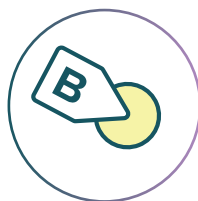
FABHALTA® is used in adults to treat patients with complement 3 glomerulopathy (C3G) together with a renin-angiotensin system inhibitor (RAS inhibitor), or alone if a RAS inhibitor does not work well or cannot be used.

FABHALTA® belongs to a group of medicines called complement inhibitors, which work by blocking specific parts of the body's immune system called the "complement system". The active substance in FABHALTA®, iptacopan, targets a protein in the complement system called Factor B and this may reduce inflammation and kidney damage caused by complement.



What happens in C3G?

In patients with C3G, the complement system is overactive, leading to deposition of C3 within the glomeruli (a part of the kidneys) causing inflammation and damage. As a result, patients with C3G often have high levels of protein in their urine (proteinuria) and progressive decline in kidney function over time.



How does FABHALTA® work?

By attaching to and blocking the Factor B protein, FABHALTA® can potentially reduce deposits of C3 in the kidneys. This helps to reduce levels of protein in the urine.

About FABHALTA® for IgAN

IgAN

What is FABHALTA®?

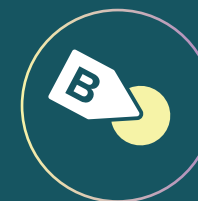
FABHALTA® is used in adults for the treatment of immunoglobulin A nephropathy (IgAN).

FABHALTA® belongs to a group of medicines called complement inhibitors, which work by blocking specific parts of the body's immune system called the "complement system". The active substance in FABHALTA®, iptacopan, targets a protein in the complement system called Factor B and this may reduce inflammation and kidney damage caused by complement.



What happens in IgAN?

In patients with IgAN, the immune system produces abnormal IgA antibodies. This causes other antibodies to attach to them, forming immune complexes that get trapped in the glomeruli (the tiny filtering units in your kidneys). The build-up of immune complexes causes inflammation and triggers the complement system to become overactive. Together, these processes can damage the kidneys over time.



How does FABHALTA® work?

By attaching to and blocking Factor B, FABHALTA® may reduce inflammation and kidney damage caused by complement. This helps to reduce levels of protein in the urine.

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.

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.

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

Vaccinations or prophylactic 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 OCTsis.

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 pneumococcal and meningococcal vaccinations at least 2 weeks before you start treatment with FABHALTA®.

If vaccination in this time is not possible, your treating physician will prescribe antibiotics to help lower the chance of developing bacterial infections. You will only be supplied FABHALTA® if your treating physician or pharmacist confirms that you are receiving the correct vaccinations or antibiotics.

To help prevent serious infections, it is important that your vaccinations are up-to-date. Your treating physician 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.

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 the package leaflet, or any other side effects, including infections, report them immediately to a healthcare professional.

Notes

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

This booklet has been produced and funded by Novartis Pharma AG.
The information provided is for educational purposes only and is not intended to replace discussions with your treating physician or care team.

You can report any problem or adverse events or request additional copies of the materials through:
Patient Safety Department Novartis Pharma AG - Saudi Arabia -.
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: <https://report.novartis.com/>



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شركة نوفارتس - السعودية - قسم سلامة المرضى:
الرقم المجاني: ٨٠٠١٢٤٠٠٧٨
الهاتف: ٠٠٩٦٦١١٢٦٥٨١٠٠
الفاكس: ٠٠٩٦٦١١٢٦٥٨١٠٧
اللايميل: adverse.events@novartis.com
أو عن طريق الإنترنت: <https://www.report.novartis.com/ar>

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Email: npc.drug@sfd.gov.sa
Or by online: <https://ade.sfd.gov.sa>



الهيئة العامة للغذاء والدواء، المركز الوطني للتبقيط الدوائي:
مركز الاتصال الموحد: ١٩٩٩٩
اللايميل: npc.drug@sfd.gov.sa
أو عن طريق الإنترنت: <https://ade.sfd.gov.sa>

Fabhalta PIL



 NOVARTIS

Novartis Saudi Limited

Building no. 7892, Secondary no. 2274
B-11 Laysen Valley
West Umm Al Hamam District
Postal Code 12329, Riyadh, SAUDI ARABIA