

Healthcare professional's guide to FABHALTA®▼ (iptacopan) IgAN and C3G

This brochure has been developed to support healthcare professionals prescribing FABHALTA®. The brochure aims to provide guidance and mitigate the possible risk of infections during FABHALTA® treatment. The brochure should be read along with your local label.

▼ FABHALTA® is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via Saudi FDA and Novartis contact details in the last page of the material.

If there are any questions or concerns about FABHALTA®, speak with a Novartis representative.



Introduction

Immunoglobulin A nephropathy:

FABHALTA® is indicated to reduce proteinuria, in addition to supportive care, in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. It has not been established whether FABHALTA slows kidney function decline in patients with IgAN.

Complement 3 glomerulopathy:

FABHALTA® is indicated for the treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

The aim of this brochure is to help mitigate possible risks associated with FABHALTA® treatment by providing a guide focusing on safety areas of concern.

Briefly, you should:

- Be aware of the risk of infection
- Ensure that your patient has received the appropriate vaccinations or prophylactic antibiotics for encapsulated bacteria and is revaccinated as recommended

Important note

You will receive bi-annual reminders of mandatory revaccinations in line with current national vaccination guidelines (including *Neisseria meningitidis*, *Streptococcus pneumoniae* and, if appropriate, *Haemophilus influenzae*).

Also, as part of the RMP, patients receiving FABHALTA® must be given the following materials to support their treatment:

- **Patient and caregiver guide**, to inform patients and caregivers about the potential risks associated with FABHALTA® treatment and their mitigation
- **Patient safety card**, containing key safety information for patients and their caregivers, as well as any healthcare professionals involved in the patient's care. This card also contains the patient identification number and emergency contact details

Please advise your patients to carry their patient safety card with them at all times during their treatment and for 2 weeks after their last dose, in case of an emergency.

What is in this guide?

p.4 Risk of serious infections

p.5 Vaccinations or prophylactic antibiotic treatment

p.6 Notes

Risk of serious infections

FABHALTA® may increase the risk of serious, life-threatening or fatal infections caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* Type B.

FABHALTA® must not be initiated in patients with unresolved serious infections caused by encapsulated bacteria.

During treatment with FABHALTA®

Monitor patients for signs and symptoms of OCTsis, meningitis or pneumonia, such as:

- **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 nausea or vomiting
 - With a stiff neck or stiff back
- **Confusion**
- **Body aches with flu-like symptoms**
- **Clammy skin**
- **Eyes sensitive to light**

If bacterial infection is suspected, treat with antibiotics immediately.

Vaccinations or prophylactic antibiotic treatment

Before starting treatment with FABHALTA®

Ensure patients are vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae* according to the current national vaccination guidelines. The *Haemophilus influenzae* Type B vaccine is recommended for patients where it is available.

Patients must be vaccinated against encapsulated bacteria at least 2 weeks before starting treatment with FABHALTA®.

If treatment with FABHALTA® must be initiated prior to vaccination, administer the necessary vaccinations as soon as possible and provide with appropriate prophylactic antibiotics should be given to the patient until 2 weeks after vaccination. This should be in accordance with current national recommendations.

Revaccinate when necessary, according to current national vaccination guidelines.

Carefully monitor patients for early signs of serious infections as the measures above reduce, but do not eliminate the risk of developing an infection. Treat any suspected infections immediately.

Additional information

Further information about FABHALTA® can be found at the SPC QR code



Notes

▼ FABHALTA® is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions to Saudi FDA and to Novartis as per the contacts below. This will allow quick identification of new safety information.

C3G, complement 3 glomerulopathy; IgA, immunoglobulin A; RAS, renin-angiotensin system; RMP, Risk Management Plan

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/>



يمكنك الإبلاغ عن أي أعراض جانبية أو شكاوى أو لطلب نسخ إضافية من خلال:
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.sfda.gov.sa>



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

SPC QR code

