

Healthcare professional's guide to **FABHALTA®** ▼ (iptacopan) for **Paroxysmal Nocturnal Hemoglobinuria (PNH)**

This brochure has been developed to support healthcare professionals prescribing FABHALTA®. The brochure aims to provide guidance and mitigate possible risk of: infections during FABHALTA® treatment, and haemolysis after discontinuation. The brochure should be read along with the Summary of Product Characteristics

Healthcare professionals are asked to report any suspected adverse reactions via

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/>



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>



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



Introduction

FABHALTA® is indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)

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 risks of infection and haemolysis
- Ensure that your patient has received the appropriate vaccinations or antibiotic prophylaxis 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 healthcare providers involved in patient care, as well as the patient identification number and your or your hospital's 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 following their last FABHALTA® dose, in case of an emergency.

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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.

- Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.
- The initiation of FABHALTA treatment is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.
- Inform patients of these signs and symptoms of serious infections and instruct patients to seek immediate medical care if these signs and symptoms occur

During treatment with FABHALTA®

Vaccinate patients as needed.

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

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

If bacterial infection is suspected, treat with antibiotics immediately.

Prophylactic vaccinations or 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 immediate treatment with FABHALTA® is required, administer the necessary vaccines as soon as possible. Additionally, 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.

Risk of serious haemolysis after discontinuing FABHALTA®

Discontinuation of FABHALTA® may increase the risk of serious haemolysis.

This means it is important to provide patients and their caregivers with advice on adherence to the dosing schedule. Patients are at risk of serious haemolysis for at least 2 weeks after discontinuing treatment with FABHALTA®. Closely monitor patients for signs and symptoms during this period.

If FABHALTA® treatment must be discontinued, alternative therapy should be considered.

Possible signs and symptoms of haemolysis include, but are not limited to:

- Elevated lactate dehydrogenase (LDH) levels along with sudden decrease in haemoglobin or PNH clone size
- Fatigue
- Haemoglobinuria
- Abdominal pain
- Dyspnoea
- Dysphagia
- Erectile dysfunction
- Major adverse vascular events, including venous or arterial thrombosis

If haemolysis occurs after discontinuation of FABHALTA®, consider restarting treatment with FABHALTA®.

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الهاتف: ٠٠٩٦٦١١٢٦٥٨١٠٠
الفاكس: ٠٠٩٦٦١١٢٦٥٨١٠٧
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الايمل: npc.drug@sfd.gov.sa
أو عن طريق الإنترنت: <https://ade.sfd.gov.sa>

Additional information

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



IPIG, International PNH Interest Group; LDH, lactate dehydrogenase; PASS, Post-Authorisation Safety Study;
PNH, paroxysmal nocturnal haemoglobinuria; RMP, Risk Management Plan.