Healthcare professional's guide to FABHALTA® (iptacopan)

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 local Package Insert.

Healthcare professionals are encouraged to report any suspected adverse reactions to Novartis at https://www.novartis.com/report or by calling Novartis at 6019 6483, or to the Vigilance and Compliance Branch, Health Products Regulation Group, Health Sciences Authority at Tel: 6866 1111, or report online at https://www.hsa.gov.sg/adverse-events

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

FABHALTA®
iptacopan

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Introduction

FABHALTA® is indicated as monotherapy for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) who have haemolytic anaemia.

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 serious encapsulated bacterial infections and haemolysis
- Ensure that your patient has received the appropriate vaccinations or antibiotic prophylaxis for encapsulated bacteria and is revaccinated as recommended

Important note

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 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.

What is in this guide?

Risk of serious infections caused by encapsulated bacteria

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.

Refer to page 5 for prescriber requirements prior to initiating treatment with FABHALTA®

During treatment with FABHALTA®

Monitor patients for signs and symptoms of sepsis, 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 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**

If bacterial infection is suspected, treat with antibiotics immediately. Serious infections may become rapidly life-threatening or fatal if not recognised and treated early

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 should 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®.

Additional information

Further information about FABHALTA® can be found at https://www.novartis.com/sg-en/product-list/fabhalta

Alternatively, please scan this QR code for more information about this medicine.

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