

Biannual Reminder: FABHALTA® Vaccination and Prophylaxis Review

Dear Healthcare Professional,

Please read carefully before prescribing the product.

This is a reminder to ensure that patients receiving FABHALTA® (iptacopan) have received the appropriate vaccinations and antibiotic prophylaxis.

Indication

FABHALTA® (iptacopan) is indicated for:

- The treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).
- The treatment of adult patients with complement 3 glomerulopathy (C3G).
- The reduction of proteinuria in adult patients with primary IgA nephropathy (IgAN) who are at risk of rapid disease progression.

FABHALTA® (iptacopan) 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.

Pre-Treatment Requirements

- Before starting treatment with FABHALTA® (iptacopan)
- 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® (iptacopan)

Immediate Treatment and Prophylaxis

If immediate treatment with FABHALTA® (iptacopan) is required:

- Administer the necessary vaccines as soon as possible.
- Appropriate prophylactic antibiotics should be given to the patient until 2 weeks after vaccination, in accordance with current national vaccination guidelines.

Monitoring and Management

- Carefully monitor patients for early signs of serious infections, as the measures above reduce, but do not eliminate, the risk of developing an infection.
- If bacterial infection is suspected, treat with antibiotics immediately.

For extra copies, please contact Novartis as per below contact details.
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**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>



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/>



Novartis Saudi Limited

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

Fabhalta SPC



FABHALTA (Iptacopan) RMP V 2.3 for C3G/IgAN and V 1.2 for PNH, Aug 2026

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