

Important Safety Information Regarding Vaccination Requirements for FABHALTA® (iptacopan)

Please read carefully before prescribing the product.

FABHALTA® (iptacopan) is a complement factor B inhibitor associated with an increased risk of serious, life-threatening, and potentially fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. Patients receiving complement inhibitors remain at risk for invasive bacterial infections even after vaccination.

Indication

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.

Vaccination and Prophylaxis Recommendations

To reduce this risk, vaccination against encapsulated bacteria should be completed or updated according to applicable immunization recommendations before initiating treatment with FABHALTA® (iptacopan), preferably at least two weeks prior to the first dose.

In circumstances where treatment cannot be delayed, appropriate preventive measures, including antibacterial prophylaxis where clinically indicated, should be considered and vaccination administered as soon as practicable.

Patient Awareness and Monitoring

Healthcare professionals are encouraged to ensure that patients are informed about the signs and symptoms of serious infection and the importance of seeking immediate medical attention should such symptoms occur. Vaccination is an important risk-mitigation measure; however, it does not eliminate the possibility of serious invasive infections during treatment with FABHALTA® (iptacopan).

This information is provided in accordance with the Saudi Food and Drug Authority-approved Risk Management Plan materials for FABHALTA® (iptacopan), which include healthcare professional educational measures aimed at minimizing the risk of serious infections associated with treatment.

Acknowledgement

I acknowledge receipt of the information provided regarding the risk of serious infections associated with FABHALTA® (iptacopan), including current recommendations for vaccination against encapsulated bacteria and related risk-mitigation considerations.

☐ I acknowledge the information provided.

Physician Name: _____

Signature: _____

Date: _____

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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Unified Contact Center: 19999
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