FABHALTA® (iptacopan) 200 mg capsules

Risk Evaluation and Mitigation Strategy (REMS)

Healthcare Provider Safety Brochure

This brochure is for healthcare providers who will prescribe or dispense FABHALTA (iptacopan).
It describes:

- What is FABHALTA?
- Prescriber Requirements
- Outpatient Pharmacy Requirements
- Inpatient Pharmacy Requirements
- What is the FABHALTA REMS?
- Adverse Event Reporting
- FABHALTA REMS Resources

If you have any questions regarding the REMS, please visit www.FABHALTA-REMS.com or call 1-833-99FABHA (1-833-993-2242)

Please see the Prescribing Information, including Boxed Warning for serious infections caused by encapsulated bacteria, for more detailed information about FABHALTA.

REMS Phone: 1-833-99FABHA (1-833-993-2242) | www.FABHALTA-REMS.com | REMS Fax: 1-877-206-3255

Reference ID: 5553884

FABHALTA (iptacopan) 200 mg capsules

What is FABHALTA?

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

FABHALTA is indicated to reduce proteinuria 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.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FABHALTA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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

Risk of serious infections caused by encapsulated bacteria

- FABHALTA increases a patient's susceptibility to 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.
- At least 2 weeks prior to the first dose of FABHALTA, complete or update vaccination against encapsulated bacteria (*Neisseria meningitidis* serogroups A, C, W, Y, and B; and *Streptococcus pneumoniae*) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.
- If urgent FABHALTA therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible.
- Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of serious infections and evaluate patients immediately if an infection is suspected. Promptly treat known infections.
- Serious infections may become rapidly life-threatening or fatal if not recognized and treated early.
- Inform patients of these signs and symptoms of serious infections and instruct patients to seek immediate medical care if these signs and symptoms occur.
- Consider interruption of FABHALTA in patients who are undergoing treatment for serious infections.

See the Prescribing Information for FABHALTA, including Boxed Warning, for more information on the risk of serious infections caused by encapsulated bacteria.

Prescriber Requirements

What do prescribers need to do to prescribe FABHALTA?

Prescribers of FABHALTA must be certified (enrolled) in the REMS to prescribe.

To become certified to prescribe FABHALTA, prescribers must:

1. Review the FABHALTA Prescribing Information
2. Review the **Healthcare Provider Safety Brochure** (this document)
3. Review the **Patient Guide**
4. Review the **Patient Safety Card**
5. Complete and submit the **Prescriber Enrollment Form** to the FABHALTA REMS
    - Online at www.FABHALTA-REMS.com, or
    - By fax at 1-877-206-3255

All materials are available on the **REMS Website** (www.FABHALTA-REMS.com) or by calling the REMS at 1-833-99FABHA (1-833-993-2242).

Prescribers will be notified within 2 business days when their certification in the FABHALTA REMS is complete, and they can prescribe FABHALTA.

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Before initiating a patient's FABHALTA treatment, prescribers must:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria and do not initiate FABHALTA therapy in any patient with these infections.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; and *Streptococcus pneumoniae* and vaccinate, as needed, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations which can be found at https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For patients who are not up to date with meningococcal and pneumococcal vaccines at least 2 weeks prior to initiation of treatment and who must start FABHALTA urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Guide** and **Patient Safety Card**. Provide a copy of the materials to the patient.
    - The **Patient Guide** provides information for your patients about the risk of serious infections.
    - The **Patient Safety Card** describes symptoms which, if experienced, should prompt the patient to seek immediate medical evaluation.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times during treatment and for 2 weeks following the last dose of FABHALTA.

During FABHALTA treatment, prescribers must:

- Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately, if infection is suspected.
- Vaccinate patients as needed according to the current ACIP recommendations.

At all times, prescribers must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.
- Comply with the FABHALTA REMS requirements to maintain certification to prescribe.
- Comply with requests from the FABHALTA REMS and its agents or contractors to support the administration of the FABHALTA REMS.

Outpatient Pharmacy Requirements

What do pharmacists need to do to dispense FABHALTA?

FABHALTA may only be dispensed by pharmacies that are certified to dispense.

To become certified to dispense FABHALTA:

- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

For the pharmacy to dispense FABHALTA, the Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document).
- **COMPLETE AND SUBMIT** the **Outpatient Pharmacy Enrollment Form** by **fax** to the FABHALTA REMS at 1-877-206-3255.

The **Outpatient Pharmacy Enrollment Form** can be obtained by calling the REMS Coordinating Center at 1-833-99FABHA (1-833-993-2242).

Pharmacies will be notified within 2 business days when their certification in the FABHALTA REMS is complete, and they can dispense FABHALTA.

By completing and submitting the Outpatient Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing FABHALTA using the **Healthcare Provider Safety Brochure**.

- Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.
- For patients who are not up to date with meningococcal and pneumococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, by contacting the prescriber before dispensing prescriptions for up to 6 months after the first dose and document the findings.

Before dispensing the first dose, all outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified by:
    - Contacting the FABHALTA REMS online (www.FABHALTA-REMS.com), or
    - Calling the REMS Coordinating Center at 1-833-99FABHA (1-833-993-2242).
- Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

For up to 6 months after dispensing the first dose, all outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified by:
    - Contacting the FABHALTA REMS online (www.FABHALTA-REMS.com), or
    - Calling the REMS Coordinating Center at 1-833-99FABHA (1-833-993-2242).
- For patients who are not initially up to date with meningococcal and pneumococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

After the first 6 months of dispensing, all outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified by:
    - Contacting the FABHALTA REMS online (www.FABHALTA-REMS.com), or
    - Calling the REMS Coordinating Center at 1-833-99FABHA (1-833-993-2242).

At all times, the outpatient pharmacy must:

- Report adverse events suggestive of serious bacterial infections to Novartis Pharmaceuticals Corporation by phone at 1-888-669-6682.
- Not distribute, transfer, loan, or sell FABHALTA, except to certified pharmacies.
- Maintain records of staff's completion of REMS training.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Novartis Pharmaceuticals Corporation or a third party acting on behalf of Novartis Pharmaceuticals Corporation to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll in the REMS by completing and submitting the **Outpatient Pharmacy Enrollment Form** to the REMS.

Inpatient Pharmacy Requirements

What do pharmacists need to do to dispense FABHALTA?

FABHALTA may only be dispensed by pharmacies that are certified to dispense.

To become certified to dispense FABHALTA:

- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

For the pharmacy to dispense FABHALTA, the Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document).
- **COMPLETE AND SUBMIT** the **Inpatient Pharmacy Enrollment Form** by **fax** to the FABHALTA REMS at 1-877-206-3255.

The **Inpatient Pharmacy Enrollment Form** can be obtained by calling the REMS Coordinating Center at 1-833-99FABHA (1-833-993-2242).

Pharmacies will be notified within 2 business days when their certification in the FABHALTA REMS is complete, and they can dispense FABHALTA.

By completing and submitting the Inpatient Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing FABHALTA using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to verify if the patient is initiating or continuing treatment.
- For patients initiating treatment: Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.

Before dispensing the first dose, all inpatient pharmacy staff must:

- Verify if the patient is initiating or continuing treatment through the processes and procedures established as a requirement of the REMS.
- For patients initiating treatment: Obtain authorization to dispense by contacting the REMS to verify the prescriber is certified.
- For patients initiating treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations, including antibacterial drug prophylaxis, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

At discharge, all inpatient pharmacy staff must:

- Dispense no more than a 30 days' supply.

At all times, the inpatient pharmacy must:

- Report adverse events suggestive of serious bacterial infections to Novartis Pharmaceuticals Corporation by phone at 1-888-669-6682.
- Not distribute, transfer, loan, or sell FABHALTA, except to certified pharmacies.
- Maintain records of staff's completion of REMS training.

- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Novartis Pharmaceuticals Corporation or a third party acting on behalf of Novartis Pharmaceuticals Corporation to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll in the REMS by completing and submitting the **Inpatient Pharmacy Enrollment Form** to the REMS.

What is the FABHALTA REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits of a drug outweigh its risks.

Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is available only through the FABHALTA REMS, a restricted distribution program.

Adverse Event Reporting

Potential cases of serious bacterial infections should be reported immediately to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

- You are encouraged to report other adverse reactions of FABHALTA to Novartis Pharmaceuticals Corporation at 1-888-669-6682 or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

FABHALTA REMS Resources

For more information about the FABHALTA REMS, visit www.FABHALTA-REMS.com or call the FABHALTA REMS at 1-833-99FABHA (1-833-993-2242).

The below resources are available for download at www.FABHALTA-REMS.com.

Prescriber

- Prescribing Information
- **Healthcare Provider Safety Brochure** (this document)
- **Prescriber Enrollment Form**

Pharmacy

- **Healthcare Provider Safety Brochure** (this document)

Pharmacies interested in certifying in the FABHALTA REMS should contact the REMS Coordinating Center at 1-833-99FABHA (1-833-993-2242).

Patient

- Medication Guide
- **Patient Guide**
- **Patient Safety Card**

This brochure does not provide complete safety information on FABHALTA. Please see the Prescribing Information, including Boxed Warning for serious infections caused by encapsulated bacteria, for the complete safety profile of FABHALTA.

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