CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218276Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
FABHALTA® (iptacopan) REMS

I. Administrative Information

Risk: serious infections caused by encapsulated bacteria
Application Number: NDA 218276
Application Holder: Novartis Pharmaceuticals Corporation
Initial REMS Approval: 12/2023

II. REMS Goal

The goal of the FABHALTA REMS is to mitigate the risk of serious infections caused by encapsulated bacteria.

1. Patients are vaccinated against infections caused by encapsulated bacteria (*Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae*; and *Haemophilus influenzae* type B) prior to starting therapy according to current Advisory Committee on Immunization Practices (ACIP) recommendations and receive antibacterial drug prophylaxis if needed.

2. Patients are aware of early signs and symptoms of serious encapsulated bacterial infections and the need for immediate medical evaluation.

3. Prescribers are aware of early signs and symptoms of serious encapsulated bacterial infections and the need for immediate medical evaluation.

III. REMS Requirements

Novartis Pharmaceuticals Corporation must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe FABHALTA must:

To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the following: Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card. 3. Enroll by completing and submitting the Prescriber Enrollment Form to the REMS.
Before treatment initiation	4. Assess the patient for unresolved serious infections caused by encapsulated bacteria. 5. For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate FABHALTA.

	6. Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae;* and *Haemophilus influenzae* type B and vaccinate, as needed, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations. 7. For patients who are not up to date with meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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. 8. Counsel the patient using the Patient Guide and Patient Safety Card. Provide a copy of the materials to the patient. 9. 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 treatment	10. Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately, if infection is suspected. 11. Revaccinate patients as needed according to the current ACIP recommendations.
At all times	12. Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation.

2. Patients who are prescribed FABHALTA:

Before treatment initiation	1. Get vaccinated as directed by your prescriber against the following encapsulated bacteria: *Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae*; and *Haemophilus influenzae* type B. 2. Take antibiotics as directed by your prescriber if you have to start FABHALTA right away. 3. Receive counseling from your prescriber using the Patient Guide and Patient Safety Card. 4. Get the Patient Guide and Patient Safety Card from your prescriber.
During treatment	5. Get additional vaccines as directed by your prescriber.
At all times during treatment and for 2 weeks after the last dose	6. Inform your prescriber or get emergency medical care right away if any of the following occur: fever with or without shivers or chills; fever and a rash; fever with chest pain and cough; fever with breathlessness/fast breathing; fever with high heart rate; headache with nausea or vomiting; headache and a fever; headache with stiff

	neck or stiff back; confusion; body aches with flu-like symptoms; clammy skin; eyes sensitive to light. 7. Have the Patient Safety Card with you.

3. Outpatient pharmacies that dispense FABHALTA must:

To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the Authorized Representative review the Healthcare Provider Safety Brochure. 3. Have the Authorized Representative enroll in the REMS by completing and submitting the Outpatient Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing FABHALTA using the Healthcare Provider Safety Brochure. 5. Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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. 6. For patients who are not up to date with meningococcal, pneumococcal, and *Haemophilus influenzae* type B vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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, first dose	7. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 8. Assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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.
Before dispensing, for up to 6 months after the first dose	9. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 10. For patients who are not initially up to date with meningococcal, pneumococcal, and *Haemophilus influenzae* type B vaccines when starting treatment: Assess the patient's vaccination status for up to

	date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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.
Before dispensing, 6 months after the first dose and thereafter	11. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
To maintain certification to dispense	12. If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the Outpatient Pharmacy Enrollment Form to the REMS.
At all times	13. Report adverse events suggestive of serious bacterial infections to Novartis Pharmaceuticals Corporation. 14. Not distribute, transfer, loan, or sell FABHALTA, except to certified pharmacies. 15. Maintain records of staff's completion of REMS training. 16. Maintain records that all processes and procedures are in place and are being followed. 17. 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.
4. Inpatient pharmacies that dispense FABHALTA must:	
To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the Authorized Representative review the Healthcare Provider Safety Brochure. 3. Have the Authorized Representative enroll in the REMS by completing and submitting the Inpatient Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing FABHALTA using the Healthcare Provider Safety Brochure. 5. Establish processes and procedures to verify if the patient is initiating or continuing treatment. 6. For patients initiating treatment: Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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, first dose	7. Verify if the patient is initiating or continuing treatment through the processes and procedures established as a requirement of the REMS. 8. For patients initiating treatment: Obtain authorization to dispense by contacting the REMS to verify the prescriber is certified. 9. For patients initiating treatment: Assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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	10. Dispense no more than a 30 days' supply.
To maintain certification to dispense	11. If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the Inpatient Pharmacy Enrollment Form to the REMS.
At all times	12. Report adverse events suggestive of serious bacterial infections to Novartis Pharmaceuticals Corporation. 13. Not distribute, transfer, loan, or sell FABHALTA, except to certified pharmacies. 14. Maintain records of staff's completion of REMS training. 15. Maintain records that all processes and procedures are in place and are being followed. 16. 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.

5. Wholesalers-distributors that distribute FABHALTA must:

To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies. 2. Train relevant staff involved in FABHALTA distribution on the REMS requirements.
At all times	3. Distribute only to certified pharmacies. 4. Maintain records of all drug distributions. 5. Comply with audits carried out by Novartis Pharmaceuticals Corporation or a third party acting on behalf of the applicant to ensure that all processes and procedures are in place and are being followed.

Novartis Pharmaceuticals Corporation must provide training to healthcare providers who prescribe FABHALTA.

The training includes the following educational materials: Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card. The training must be available online and by hard copy via fax and mail.

Novartis Pharmaceuticals Corporation must provide training to pharmacies that dispense FABHALTA.

The training includes the following educational material: Healthcare Provider Safety Brochure. The training must be available online and by hard copy via fax, and mail.

To support REMS operations, Novartis Pharmaceuticals Corporation must:

1. Establish and maintain a REMS Website, www.FABHALTA-REMS.com. The REMS Website must include the capability to complete prescriber certification online and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Website. The REMS Website must not link back to the promotional product website(s).

2. Make the REMS Website fully operational and all REMS materials available through the REMS Website and REMS Coordinating Center by the date FABHALTA is first commercially distributed.

3. Establish and maintain a REMS Coordinating Center for REMS participants at 1-833-99FABHA (1-833-993-2242).

4. Establish and maintain a validated, secure database of all REMS participants who are certified in the FABHALTA REMS.

5. Ensure prescribers are able to enroll in the REMS by fax and online.

6. Ensure pharmacies are able to enroll in the REMS by fax.

7. Ensure pharmacies are able to obtain authorization to dispense by phone or online.

8. Ensure prescribers and pharmacies are able to report adverse events suggestive of serious bacterial infections by phone.

9. Ensure that once an adverse event suggestive of serious bacterial infection is received, Novartis Pharmaceuticals Corporation will follow-up with the healthcare provider to obtain all required data. This requirement does not affect Novartis Pharmaceuticals Corporation's other reporting and follow-up requirements under FDA regulations.

10. Provide the Healthcare Provider Safety Brochure, Prescriber Enrollment Form, Patient Guide, Patient Safety Card, and the Prescribing Information to prescribers who (1) attempt to prescribe FABHALTA and are not yet certified or (2) inquire about how to become certified.

11. Provide the Healthcare Provider Safety Brochure and Outpatient Pharmacy Enrollment Form or Inpatient Pharmacy Enrollment Form to pharmacies who (1) attempt to order/dispense and are not yet certified or (2) inquire about how to become certified.

12. Notify prescribers and pharmacies within 2 business days after they become certified in the REMS.

13. Provide certified outpatient pharmacies access to the database of certified prescribers.

14. Provide certified prescribers access to the database of certified pharmacies.

15. Provide authorized wholesalers-distributors access to the database of certified pharmacies.

To ensure REMS participants' compliance with the REMS, Novartis Pharmaceuticals Corporation must:

16. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to, records of: FABHALTA distribution and dispensing; certification of prescribers and pharmacies; and audits of REMS participants. These records must be readily available for FDA inspections.

17. Verify annually that the designated Authorized Representative's name and contact information correspond to those of the current designated Authorized Representative for the pharmacy. If different, the pharmacy must be required to re-certify with a new Authorized Representative.

18. Establish and maintain a plan for addressing noncompliance with REMS requirements.

19. Monitor prescribers and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including decertification.

20. Audit certified outpatient and inpatient pharmacies no later than 180 calendar days after they receive their first shipment and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and comply with REMS requirements.

21. Audit wholesalers-distributors no later than 180 calendar days after their first commercial distribution of FABHALTA and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and comply with REMS requirements.

22. Take reasonable steps to improve operations of and compliance with the requirements of the FABHALTA REMS based on monitoring and evaluation of the FABHALTA REMS.

IV. REMS Assessment Timetable

Novartis Pharmaceuticals Corporation must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Novartis Pharmaceuticals Corporation must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the FABHALTA REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Pharmacy:

2. Outpatient Pharmacy Enrollment Form
3. Inpatient Pharmacy Enrollment Form

Training and Educational Materials

Prescriber:

4. Healthcare Provider Safety Brochure

Patient:

5. Patient Guide
6. Patient Safety Card

Pharmacy:

7. Healthcare Provider Safety Brochure

Other Materials

8. REMS Website

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use:
   - Health care providers who prescribe FABHALTA are specially certified under 505-1(f)(3)(A)
   - Pharmacies that dispense FABHALTA are specially certified under 505-1(f)(3)(B)
   - FABHALTA is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
2. Implementation System
3. Timetable for Submission of Assessments

FABHALTA® REMS

Prescriber Enrollment Form

FABHALTA (iptacopan) 200 mg capsules

Instructions:
To become certified in the FABHALTA REMS, prescribers must:

1. Review the FABHALTA Prescribing Information
2. Review the REMS materials:
   - **Healthcare Provider Safety Brochure**
   - **Patient Guide**
   - **Patient Safety Card**
3. Submit this completed form to the FABHALTA REMS:
   - Online at www.FABHALTA-REMS.com, or
   - By fax at 1-877-206-3255

Prescriber Information ***(*indicates required field)***		
*First Name:	Middle Initial:	*Last Name:
*National Provider Identifier (NPI) #:		
*Specialty (select one): ☐ Hematology/Oncology ☐ Immunology ☐ Internal Medicine ☐ Nephrology ☐ Neurology ☐ Rheumatology ☐ Other (please specify): _____		
*Credentials (select one): ☐ MD ☐ DO ☐ PA ☐ APRN ☐ Other (please specify): _____		
Office Practice/Clinic Name:		
*Address Line #1:		
Address Line #2:		
*City:	*State:	*Zip:
Preferred Method of Contact (select one): ☐ Fax ☐ Email		
*Email:	*Office Phone:	
*Office Fax:	Alternative Office Phone:	

Primary Office Contact Information	
First Name:	Last Name:
Title:	
Office Phone:	Office Fax:
*Email (required if Office Contact is provided):	
Preferred Method of Contact (select one): ☐ Fax ☐ Email	

Reference ID: 5288334

Prescriber Attestations

By completing, signing, and submitting this form, I acknowledge and agree that:

I have read and understand the FABHALTA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Guide**, and **Patient Safety Card**.

Before treatment initiation, I must:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate FABHALTA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae*; and *Haemophilus influenzae* type B and vaccinate, as needed, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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.
- 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 treatment, I must:

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

At all times, I must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation by phone at 1-888-669-6682.

I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe FABHALTA.

I understand that the FABHALTA REMS and its agents or contractors may contact me to support the administration of the REMS.

By completing and submitting this form as directed above and receiving certification confirmation, you will be certified in the REMS. You will receive confirmation of your certification via your preferred method of contact.

*Prescriber Signature:	*Signature Date (MM-DD-YYYY):

FABHALTA® REMS

Outpatient Pharmacy Enrollment Form

FABHALTA (iptacopan) 200 mg capsules

Instructions:

1. Designate an Authorized Representative to complete training and to commit to training all staff who will be involved in dispensing FABHALTA.
2. Review the **Healthcare Provider Safety Brochure**.
3. Submit this completed form by fax to 1-877-206-3255.

REMS Pharmacy Information		
☐ Initial pharmacy enrollment ☐ Change of information for enrolled pharmacy ☐ Change of Authorized Representative		
Authorized Representative Information *(*indicates required field)*		
*First Name:	Middle Initial:	*Last Name:
*Title/position:		
Preferred Method of Contact (select one): ☐ Fax ☐ Email		
*Email:	*Office Phone:	
*Office Fax:	Alternative Office Phone:	
Outpatient Pharmacy Information *(*indicates required field)*		
*Pharmacy Name:		
*Pharmacy Address Line #1:		
Address Line #2:		
*National Provider Identifier (NPI) #:		
*City:	*State:	*Zip:
*Pharmacy Phone:	*Pharmacy Fax:	

Reference ID: 5288334

Authorized Representative Attestations

By signing below, I agree that I have read this Pharmacy Agreement and understand my obligations as the Authorized Representative designated by this pharmacy.

As the Authorized Representative, I must:

- Review the **Healthcare Provider Safety Brochure**.
- 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, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal, pneumococcal and *Haemophilus influenzae* type B 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.
- Assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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.
- For patients who are not initially up to date with meningococcal, pneumococcal, and *Haemophilus influenzae* type B vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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.

At all times, my 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 this **Outpatient Pharmacy Enrollment Form** to the REMS.

I understand that if the pharmacy does not maintain compliance with the requirements of the REMS, the pharmacy will no longer be able to dispense FABHALTA.

I understand that the FABHALTA REMS and its agents or contractors may contact me to support the administration of the REMS.

By completing and submitting this form as directed above and receiving certification confirmation, your pharmacy will be certified in the FABHALTA REMS. You will receive confirmation of your certification via your preferred method of contact.

*Authorized Representative Signature:	*Signature Date (MM-DD-YYYY):

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

FABHALTA® REMS

Inpatient Pharmacy Enrollment Form

FABHALTA (iptacopan) 200 mg capsules

Instructions:

1. Designate an Authorized Representative to complete training and to commit to training all staff who will be involved in dispensing FABHALTA.
2. Review the **Healthcare Provider Safety Brochure**.
3. Complete and submit this form by fax to 1-877-206-3255.

REMS Pharmacy Information		
☐ Initial pharmacy enrollment ☐ Change of information for enrolled pharmacy ☐ Change of Authorized Representative		
Authorized Representative Information *(*indicates required field)*		
*First Name:	Middle Initial:	*Last Name:
*Title/position:		
Preferred Method of Contact (select one): ☐ Fax ☐ Email		
*Email:	*Office Phone:	
*Office Fax:	Alternative Office Phone:	
Inpatient Pharmacy Information *(*indicates required field)*		
*Inpatient Pharmacy Name:		
*Inpatient Pharmacy Location: ☐ Hospital ☐ Nursing Home ☐ Hospice ☐ Mental Health Facility ☐ Assisted Living ☐ Prison ☐ Rehabilitation Facility ☐ Other (please specify):_____		
*Inpatient Pharmacy Address Line #1:		
Address Line #2:		
*National Provider Identifier (NPI) #:		
*City:	*State:	*Zip:
*Pharmacy Phone:	*Pharmacy Fax:	

Reference ID: 5288334

Authorized Representative Attestations

By signing below, I agree that I have read this Pharmacy Agreement and understand my obligations as the Authorized Representative designated by this pharmacy.

As the Authorized Representative, I must:

- Review the **Healthcare Provider Safety Brochure**.
- 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, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B 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, my 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 this **Inpatient Pharmacy Enrollment Form** to the REMS.

I understand that if the pharmacy does not maintain compliance with the requirements of the REMS, the pharmacy will no longer be able to dispense FABHALTA.

I understand that the FABHALTA REMS and its agents or contractors may contact me to support the administration of the REMS.

By completing and submitting this form as directed above and receiving certification confirmation, your pharmacy will be certified in the FABHALTA REMS. You will receive confirmation of your certification via your preferred method of contact.

*Authorized Representative Signature:	*Signature Date (MM-DD-YYYY):

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

NOVARTIS

Novartis Pharmaceuticals Corporation
One Health Plaza, East Hanover, New Jersey 07936-1080

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

FABHALTA (iptacopan) 200 mg capsules

What is FABHALTA?

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

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, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B) 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.

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; *Streptococcus pneumoniae*; and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B and 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.
- Revaccinate 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, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B 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, pneumococcal, and *Haemophilus influenzae* type B 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.

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

NOVARTIS

Novartis Pharmaceuticals Corporation
One Health Plaza, East Hanover, New Jersey 07936-1080

12/2023 373211

FABHALTA®
(iptacopan) 200 mg capsules

Patient Guide

Risk Evaluation and Mitigation Strategy (REMS)

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

Reference ID: 5288334

What is FABHALTA®?

FABHALTA (iptacopan) is a prescription medicine used to treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH).

What is the serious risk of FABHALTA?

FABHALTA may lower the ability of your immune system to fight infections.

FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria. Serious infections may quickly become life-threatening and cause death if not recognized and treated early.

Call your healthcare provider or **get emergency medical care right away** if you have any of these signs and symptoms of a serious infection:

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

Talk to your doctor about other side effects of FABHALTA and review the FABHALTA Medication Guide for more information.

Getting your vaccines

- Your doctor will review your vaccine history before starting treatment with FABHALTA and let you know which vaccines you need.
- Complete or update your vaccinations as directed by your doctor at least 2 weeks before your first dose of FABHALTA.
- If your doctor decides that treatment with FABHALTA must be started right away and you have not completed your vaccinations:
  - Your doctor will select an antibiotic for you to take.
  - You must receive a prescription for antibiotics from your doctor.
  - You should receive the vaccines as soon as possible.
- Vaccines do not prevent all serious infections. These infections may still occur. You will need to watch for signs and symptoms of serious infections even after receiving the vaccines.
- During treatment with FABHALTA, you might need to get additional vaccines as directed by your doctor.

FABHALTA® (iptacopan) 200 mg capsules

Patient Safety Card

- Your doctor will give you a **Patient Safety Card** about the risk of serious infections.
- Keep the card with you at all times during treatment and for 2 weeks after the last dose of FABHALTA. Your risk of serious infections may continue for a few weeks after your last dose of FABHALTA.
- Call your doctor or get emergency medical care right away if you have any of the signs or symptoms of a serious infection that are described in this **Patient Guide**.
- Show this card to any healthcare provider who treats you.
    - This card lets them know about your FABHALTA treatment and will help them diagnose and treat you quickly.

What is the FABHALTA REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. When there is a REMS, drug companies, healthcare providers, and pharmacies must take extra steps to make sure the benefits of using the drug are greater than the risks.

FABHALTA has a REMS because it can increase your chance of getting serious infections caused by encapsulated bacteria. Serious infections may quickly become life-threatening and cause death if not recognized and treated early.

How will I get my FABHALTA medicine?

Only certain pharmacies can fill your FABHALTA prescription. The pharmacies that are part of the FABHALTA REMS will contact you to fill your prescription for FABHALTA and ship it to your preferred address.

Who can I contact with questions about the FABHALTA REMS?

If you have questions about the FABHALTA REMS, you can call the FABHALTA REMS.

Phone: 1-833-99FABHA (1-833-993-2242)

Hours of Operation:

8:00 AM – 8:00 PM Eastern

www.FABHALTA-REMS.com

If you have any questions about your health or medicines, talk to your healthcare provider.

To report side effects, contact Novartis Pharmaceuticals, Inc. at 1-888-669-6682, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

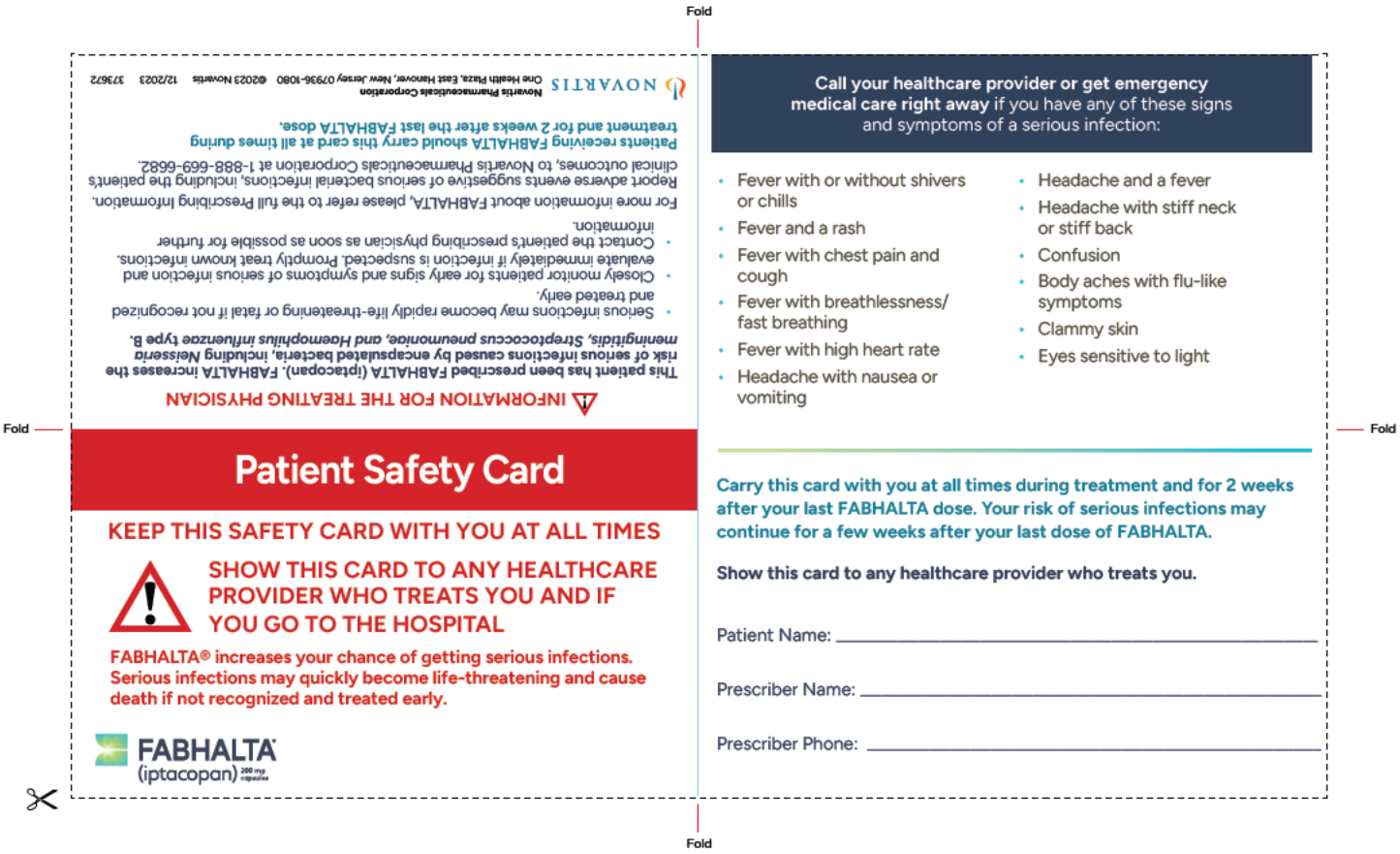
REMS Phone: 1-833-99FABHA (1-833-993-2242) | www.FABHALTA-REMS.com | REMS Fax: 1-877-206-3255

NOVARTIS

Novartis Pharmaceuticals Corporation
One Health Plaza, East Hanover, New Jersey 07936-1080

12/2023 373667

Reference ID: 5288334



Print out, cut along the dotted lines and fold in half and half again.

This site is intended for US residents only

FABHALTA (iptacopan) 200 mg capsules

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FABHALTA® REMS

What is the FABHALTA REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a safety program required by the Food and Drug Administration (FDA) to ensure the potential benefits of FABHALTA outweigh its risks. FABHALTA has a REMS because of the risk of serious infections caused by encapsulated bacteria.

What is the Goal of the FABHALTA REMS?

The goal of the FABHALTA REMS is to mitigate the risk of serious infections caused by encapsulated bacteria.

1. Patients are vaccinated against infections caused by encapsulated bacteria (*Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae;* and *Haemophilus influenzae* type B) prior to starting therapy according to current Advisory Committee on Immunization Practices (ACIP) recommendations and receive antibacterial drug prophylaxis if needed.
2. Patients are aware of early signs and symptoms of serious encapsulated bacterial infections and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of serious encapsulated bacterial infections and the need for immediate medical evaluation.

FABHALTA is available only through the FABHALTA REMS, a restricted distribution program.

What does FABHALTA treat?

FABHALTA is a complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

For FABHALTA REMS information contact:
REMS Phone: **1-833-99FABHA (1-833-993-2242)**
REMS Fax: **1-877-206-3255**

Privacy Policy | Terms of Use

Healthcare providers should report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

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Prescriber

Program Requirements for Prescribers

Due to the risk of serious infections caused by encapsulated bacteria associated with FABHALTA, prescribers must be educated on the risk and how to mitigate the risk in order to prescribe FABHALTA. Prescribers must be certified to prescribe FABHALTA.

To become certified, prescribers must complete the following steps:

1	2	3
Review the Prescribing Information	Review the REMS materials: • **Healthcare Provider Safety Brochure** • **Patient Guide** • **Patient Safety Card**	Submit the completed **Prescriber Enrollment Form**: • Online, or • By fax to 1-877-206-3255

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

Key Prescriber Requirements:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate FABHALTA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae;* and *Haemophilus influenzae* type B and vaccinate, as needed, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal, pneumococcal, and *Haemophilus influenzae* type B vaccines at least 2 weeks prior to initiation of treatment and who must start FABHATA 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.

Steps the prescriber should take prior to initiating treatment with FABHALTA, during treatment with FABHALTA, and at all times are included in the **Healthcare Provider Safety Brochure**.

Prescribers who do not maintain compliance with the requirements of the FABHALTA REMS, will no longer be able to prescribe FABHALTA.

Prescriber Online Enrollment

FABHALTA® REMS

Prescriber Enrollment Form

Instructions

To become certified in the FABHALTA REMS, prescribers must:

1. Review the FABHALTA Prescribing Information
2. Review the REMS materials:
   - **Healthcare Provider Safety Brochure**
   - **Patient Guide**
   - **Patient Safety Card**
3. Submit this completed **Prescriber Enrollment Form** to the FABHALTA REMS:
   - Online below, or
   - By fax to 1-877-206-3255

(**indicates required field*)

Prescriber Information

* National Provider Identifier (NPI) #

Continue

Healthcare providers should report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

Prescriber Online Enrollment

FABHALTA® REMS
Prescriber Enrollment Form

Instructions

To become certified in the FABHALTA REMS, prescribers must:

1. Review the FABHALTA Prescribing Information
2. Review the REMS materials:
   - **Healthcare Provider Safety Brochure**
   - **Patient Guide**
   - **Patient Safety Card**
3. Submit this completed **Prescriber Enrollment Form** to the FABHALTA REMS:
   - Online below, or
   - By fax to 1-877-206-3255

(**indicates required field*)

Prescriber Information

* National Provider Identifier (NPI) #
1234567890

* First Name: Steve | Middle Initial | * Last Name: Meru

* Specialty (select one)
○ Hematology/Oncology ○ Immunology ○ Internal Medicine ○ Nephrology ○ Neurology
○ Rheumatology ○ Other (please specify)

* Credentials (select one)
○ MD ○ DO ○ PA ○ APRN ○ Other (please specify)

Office Practice / Clinic Name

* Address Line #1 | Address Line #2

* City | * State: -- Please Select -- | * Zip

Preferred Method of Contact (select one)
○ Fax ○ Email

* Email | * Office Phone | * Office Fax

Alternative Office Phone

Primary Office Contact Information

Note: First Name, Last Name and Email are required if Primary Office Contact is provided.

First Name | Last Name | Email

Title | Office Phone | Office Fax

Preferred Method of Contact (select one)
○ Fax ○ Email

Prescriber Attestations

By completing, signing, and submitting this form, I acknowledge and agree that:

I have read and understand the FABHALTA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Guide**, and **Patient Safety Card**.

Before treatment initiation, I must:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate FABHALTA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae*; and *Haemophilus influenzae* type B and vaccinate, as needed, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal, pneumococcal and *Haemophilus influenzae* type B vaccines at least 2 weeks prior to initiation of treatment and who must start FABHATA 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.
- 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 treatment, I must:

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

At all times, I must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation by phone at 1-888-669-6682.

I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe FABHALTA.

I understand that the FABHALTA REMS and its agents or contractors may contact me to support the administration of the REMS.

By completing and submitting this form as directed above and receiving certification confirmation, you will be certified in the REMS. You will receive confirmation of your certification via your preferred method of contact.

Clear Signature

Please use your mouse or stylus to sign below

Cancel | Submit

Prescriber Online Enrollment

FABHALTA® REMS
Prescriber Enrollment Form

Instructions

To become certified in the FABHALTA REMS, prescribers must:

1. Review the FABHALTA Prescribing Information
2. Review the REMS materials:
   - **Healthcare Provider Safety Brochure**
   - **Patient Guide**
   - **Patient Safety Card**
3. Submit this completed **Prescriber Enrollment Form** to the FABHALTA REMS:
   - Online below, or
   - By fax to 1-877-206-3255

*(*indicates required field)*

Prescriber Information

*National Provider Identifier (NPI) #
1234567890

*First Name: Steve | Middle Initial | *Last Name: Meru

*Specialty (select one)
○ Hematology/Oncology ○ Immunology ○ Internal Medicine ○ Nephrology ○ Neurology
○ Rheumatology ◉ Other (please specify)

*Specialty Other
Other

*Credentials (select one)
○ MD ○ DO ○ PA ○ APRN ◉ Other (please specify)

*Credentials Other
Other

Office Practice / Clinic Name

*Address Line #1 | Address Line #2

*City | *State -- Please Select -- | *Zip

Prefered Method of Contact (select one)
○ Fax ○ Email

*Email | *Office Phone | *Office Fax

Alternative Office Phone

Primary Office Contact Information

Note: First Name, Last Name and Email are required if Primary Office Contact is provided.

*First Name: Mark | *Last Name | *Email

Title | Office Phone | Office Fax

Prefered Method of Contact (select one)
○ Fax ○ Email

Prescriber Attestations

By completing, signing, and submitting this form, I acknowledge and agree that:

I have read and understand the FABHALTA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Guide** and **Patient Safety Card**.

Before treatment initiation, I must:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate FABHALTA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; *Streptococcus pneumoniae*; and *Haemophilus influenzae* type B and vaccinate, as needed, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal, pneumococcal and *Haemophilus influenzae* type B vaccines at least 2 weeks prior to initiation of treatment and who must start FABHATA 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.
- 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 treatment, I must:

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

At all times, I must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation by phone at 1-888-669-6682.

I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe FABHALTA.

I understand that the FABHALTA REMS and its agents or contractors may contact me to support the administration of the REMS.

By completing and submitting this form as directed above and receiving certification confirmation, you will be certified in the REMS. You will receive confirmation of your certification via your preferred method of contact.

Clear Signature

Please use your mouse or stylus to sign below

Cancel Submit

Healthcare providers should report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

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Prescriber Online Enrollment

Thank you for submitting your information to certify in the FABHALTA REMS.

A confirmation of this submission has been sent via your preferred method of contact.

If you do not receive the email within the next few hours, or would like to update your enrollment information at any time, please contact the FABHALTA REMS at 1-833-99FABHA (1-833-993-2242).

Healthcare providers should report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

Outpatient Pharmacy

Program Requirements for Outpatient Pharmacies

FABHALTA is only available through the FABHALTA REMS because of the risk of serious infections caused by encapsulated bacteria. All outpatient pharmacies must become certified in the REMS in order to dispense FABHALTA.

To become certified in the FABHALTA REMS, an outpatient pharmacy must designate an Authorized Representative. The Authorized Representative must:

1

Review the **Healthcare Provider Safety Brochure**

2

Complete and submit the **Outpatient Pharmacy Enrollment Form** to the FABHALTA REMS

- Pharmacies must contract with Novartis and complete and submit an **Outpatient Pharmacy Enrollment Form** prior to becoming certified
- Contact the FABHALTA REMS Coordinating Center at **1-833-99FABHA (1-833-993-2242)** to obtain the **Outpatient Pharmacy Enrollment Form**

3

Oversee the implementation and compliance with the REMS requirements on behalf of the outpatient pharmacy

Steps pharmacy staff should take prior to dispensing FABHALTA, and at all times, are included in the **Healthcare Provider Safety Brochure**.

Inpatient Pharmacy

Program Requirements for Inpatient Pharmacies

FABHALTA is only available through the FABHALTA REMS because of the risk of serious infections caused by encapsulated bacteria. FABHALTA is only available from pharmacies that are certified in the FABHALTA REMS.

To become certified, the inpatient pharmacy must designate an Authorized Representative. The Authorized Representative must:

1

Review the **Healthcare Provider Safety Brochure**

2

Complete and submit the **Inpatient Pharmacy Enrollment Form** to the FABHALTA REMS

- Contact the FABHALTA REMS Coordinating Center at **1-833-99FABHA (1-833-993-2242)** to obtain the **Inpatient Pharmacy Enrollment Form**
- Pharmacies must complete and submit an **Inpatient Pharmacy Enrollment Form** prior to becoming certified

3

Oversee the implementation and compliance with the REMS requirements on behalf of the inpatient pharmacy

Steps pharmacy staff should take prior to dispensing FABHALTA, and at all times, are included in the **Healthcare Provider Safety Brochure**.

Healthcare providers should report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

This site is intended for US residents only

FABHALTA (iptacopan) 200 mg capsules

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Certified Pharmacy Locator

Below is a list of pharmacies certified in the FABHALTA REMS to dispense FABHALTA.

Pharmacy Name	Pharmacy Type	City	State	Phone Number
	-- Please Select --		-- Please Select --	
ABC Pharmacy	Inpatient Pharmacy	Philadelphia	PA	555 555-1212
XYZ Pharmacy	Outpatient Pharmacy	Philadelphia	PA	555 555-3434

For FABHALTA REMS information contact:
REMS Phone: **1-833-99FABHA (1-833-993-2242)**
REMS Fax: **1-877-206-3255**

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Healthcare providers should report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

Contact Us

FABHALTA REMS Coordinating Center

Phone	Fax	Hours of Operation
1-833-99FABHA (1-833-993-2242)	1-877-206-3255	Monday – Friday, 8 AM – 8 PM ET

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Resources

Prescriber

- Prescribing Information
- **Healthcare Provider Safety Brochure**
- **Prescriber Enrollment Form**

Pharmacy

- **Healthcare Provider Safety Brochure**

Pharmacies interested in getting certified 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**

Advisory Committee on Immunization Practices (ACIP) recommendations can be found at https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.

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/s/

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