Novartis
Patient Support™

Guide to completing the Start Form

Novartis Patient Support provides comprehensive resources designed to help your patients start, stay, and save on FABHALTA® (iptacopan).

Not an actual patient.

INDICATIONS

FABHALTA is indicated for:

- The treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- The reduction of 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.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

FABHALTA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life threatening or fatal if not recognized and treated early.

- **Complete or update vaccinations for encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, unless the risks of delaying therapy with FABHALTA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving FABHALTA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the FABHALTA REMS.

Please see full Important Safety Information and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Novartis Patient Support

Your patients are our top priority

Novartis Patient Support provides comprehensive resources that can help your eligible patients start, stay, and save on FABHALTA® (iptacopan).

We can help get your eligible patients started and guide them along the way with:

- Dedicated assistance with insurance and reimbursement
- Personalized support for your patients on therapy
- Single point of contact for you and your patients

Our offerings include:

Insurance Support

Help navigating the insurance process, including benefits verification and support with prior authorization and appeals process.

Financial Support

Inform your eligible patients about **Co-Pay Plus.*** Privately insured patients may pay as little as $0 for FABHALTA® (iptacopan).

Vaccination Support†

Our dedicated Novartis Patient Support team offers support to help your patients locate vaccinations.

Ongoing Support

A dedicated Novartis Patient Support team and educational resources to help your patients get started on treatment and support them along the way.

***Co-Pay Plus:** Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Patients with commercial insurance coverage for FABHALTA may receive up to $20,000 in annual co-pay benefits for the cost of FABHALTA and up to $1,000 for qualifying vaccination costs. Patients with commercial insurance and a prior authorization requirement may receive up to 12 months of free product while coverage is pursued. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at www.fabhalta.com for details.

†**Vaccination Support:** Limitations apply. Please contact Novartis Patient Support at 1-833-99FABHA (1-833-993-2242) for more information.

Questions?
Call Novartis Patient Support at 1-833-99FABHA (1-833-993-2242), Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays.
Visit www.fabhalta.com for more information.

The information herein is provided for educational purposes only. Novartis cannot guarantee health plan or reimbursement. Coverage and reimbursement may vary significantly by health plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see full Important Safety Information and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Novartis Patient Support

Getting patients started

Novartis Patient Support will work with your practice to help your eligible patient start on FABHALTA® (iptacopan). Begin the process by completing the Start Form. We have outlined the key information below to help ensure a smoother process for your office and your patient.

Page 1

Novartis Patient Support™

FABHALTA® (iptacopan) START FORM

* = REQUIRED FIELDS

Please fill out all fields on this form to enroll in Novartis Patient Support.

1. Patient Information

First Name* Last Name* Email

Date of Birth (MM/DD/YYYY)* Sex for Clinical Use*: ☐ Male ☐ Female Phone Number*† — We'll keep you updated through non-marketing calls and texts. ☐ Mobile ☐ Home

Address (No PO Box)* OK to Leave Voicemail: ☐ Yes ☐ No

City State ZIP* Preferred Language: ☐ English ☐ Spanish ☐ Other:

I give permission to disclose my personal health information to the following Caregiver (optional):

Caregiver Name Relationship to Patient

Caregiver Phone Number — We'll keep you updated through non-marketing calls and texts.

2. Patient Authorization and Additional Enrollment Consents

I have read and agree to the Patient Authorization on page 3.

→ X

Patient/Authorized Representative Signature* Date (MM/DD/YYYY)*

☐ Check here if signed by an Authorized Representative.

CO-PAY PLUS

If you have private insurance, you may be eligible for the $0 Co-Pay Plus Offer by checking the box below.

☐ I have read and agree to the Co-Pay Plus Terms and Conditions on page 3.

ONGOING SUPPORT FROM NOVARTIS PATIENT SUPPORT

You can also get continued one-on-one support from your dedicated Novartis Patient Support team by checking the box below.

☐ I agree to receive marketing calls and texts from and on behalf of Novartis and its affiliates, including calls and texts made with an autodialer or prerecorded voice, at the phone number(s) I provide. I understand that my consent is not required and is not a condition of receiving any goods or services from Novartis.

3. Insurance Information

To prevent delays, please include copies (front and back) of the patient's prescription insurance card(s). Include primary, secondary, and prescription insurance, if separate from medical insurance.

Check all that apply*: ☐ Primary ☐ Secondary ☐ Prescription ☐ Patient Is Uninsured

4. Prescriber Information

First Name* Last Name* Practice Name

Address Practice Phone Number

City State ZIP* Office Contact Name Office Contact Phone

Prescriber NPI Number* Office Fax* Office Email

Send Fax 1-877-44FABHA (1-877-443-2242) Questions? Call 1-833-99FABHA (1-833-993-2242)

Complete entire form and fax to Novartis Patient Support at 1-877-44FABHA (1-877-443-2242).

An incomplete Start Form may delay the start of treatment.

Page 1 of 3

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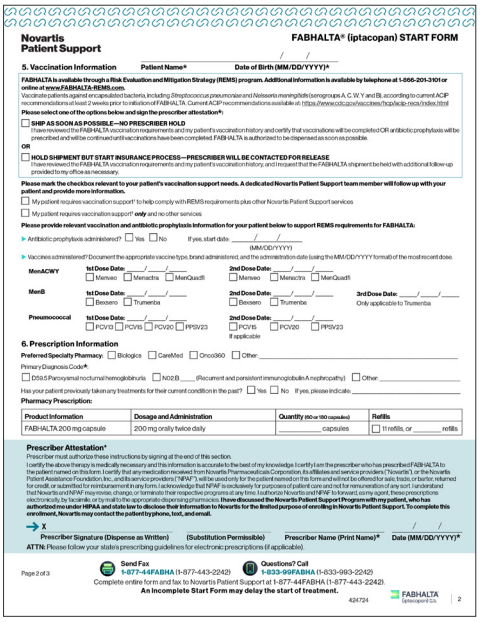
FABHALTA (iptacopan) 200 mg capsules

1

Page 2



Novartis Patient Support

FABHALTA® (iptacopan) START FORM

5. Vaccination Information Patient Name* Date of Birth (MM/DD/YYYY)*

FABHALTA is available through a Risk Evaluation and Mitigation Strategy (REMS) program. Additional information is available by telephone at 1-866-201-3101 or online at www.FABHALTA-REMS.com.

Vaccinate patients against encapsulated bacteria, including Streptococcus pneumoniae and Neisseria meningitidis (serogroups A, C, W, Y, and B), according to current ACIP recommendations at least 2 weeks prior to initiation of FABHALTA. Current ACIP recommendations available at: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

Please select one of the options below and sign the prescriber attestation®:

☐ SHIP AS SOON AS POSSIBLE—NO PRESCRIBER HOLD

I have reviewed the FABHALTA vaccination requirements and my patient's vaccination history and certify that vaccinations will be completed OR antibiotic prophylaxis will be prescribed and will be continued until vaccinations have been completed. FABHALTA is authorized to be dispensed as soon as possible.

OR

☐ HOLD SHIPMENT BUT START INSURANCE PROCESS—PRESCRIBER WILL BE CONTACTED FOR RELEASE

I have reviewed the FABHALTA vaccination requirements and my patient's vaccination history, and I request that the FABHALTA shipment be held with additional follow-up provided to my office as necessary.

Please mark the checkbox relevant to your patient's vaccination support needs. A dedicated Novartis Patient Support team member will follow up with your patient and provide more information.

☐ My patient requires vaccination support† to help comply with REMS requirements plus other Novartis Patient Support services

☐ My patient requires vaccination support† **only** and no other services

Please provide relevant vaccination and antibiotic prophylaxis information for your patient below to support REMS requirements for FABHALTA:

▶ Antibiotic prophylaxis administered? ☐ Yes ☐ No If yes, start date ____/____/____ (MM/DD/YYYY)

▶ Vaccines administered? Document the appropriate vaccine type, brand administered, and the administration date (using the MM/DD/YYYY format) of the most recent dose.

MenACWY	1st Dose Date: ____/____/____ ☐ Menveo ☐ Menactra ☐ MenQuadfi	2nd Dose Date: ____/____/____ ☐ Menveo ☐ Menactra ☐ MenQuadfi
MenB	1st Dose Date: ____/____/____ ☐ Bexsero ☐ Trumenba	2nd Dose Date: ____/____/____ ☐ Bexsero ☐ Trumenba
		3rd Dose Date: ____/____/____ Only applicable to Trumenba
Pneumococcal	1st Dose Date: ____/____/____ ☐ PCV13 ☐ PCV15 ☐ PCV20 ☐ PPSV23	2nd Dose Date: ____/____/____ ☐ PCV15 ☐ PCV20 ☐ PPSV23 If applicable

6. Prescription Information

Preferred Specialty Pharmacy: ☐ Biologics ☐ CareMed ☐ Onco360 ☐ Other:

Primary Diagnosis Code*:

☐ D59.5 Paroxysmal nocturnal hemoglobinuria ☐ N02.B _____ (Recurrent and persistent immunoglobulin A nephropathy) ☐ Other:

Has your patient previously taken any treatments for their current condition in the past? ☐ Yes ☐ No If yes, please indicate:

Pharmacy Prescription:

Product Information	Dosage and Administration	Quantity (60 or 180 capsules)	Refills
FABHALTA 200 mg capsule	200 mg orally twice daily	_____ capsules	☐ 11 refills, or _____ refills

Prescriber Attestation*

Prescriber must authorize these instructions by signing at the end of this section.

I certify the above therapy is medically necessary and this information is accurate to the best of my knowledge. I certify I am the prescriber who has prescribed FABHALTA to the patient named on this form. I certify that any medication received from Novartis Pharmaceuticals Corporation, its affiliates and service providers ("Novartis"), or the Novartis Patient Assistance Foundation, Inc., and its service providers ("NPAF"), will be used only for the patient named on this form and will not be offered for sale, trade, or barter, returned for credit, or submitted for reimbursement in any form. I acknowledge that NPAF is exclusively for purposes of patient care and not for remuneration of any sort. I understand that Novartis and NPAF may revoke, change, or terminate their respective programs at any time. I authorize Novartis and NPAF to forward, as my agent, these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies. **I have discussed the Novartis Patient Support Program with my patient, who has authorized me under HIPAA and state law to disclose their information to Novartis for the limited purpose of enrolling in Novartis Patient Support. To complete this enrollment, Novartis may contact the patient by phone, text, and email.**

→ X

Prescriber Signature (Dispense as Written) (Substitution Permissible) Prescriber Name (Print Name)* Date (MM/DD/YYYY)*

ATTN: Please follow your state's prescribing guidelines for electronic prescriptions (if applicable).

Page 2 of 3

Send Fax 1-877-44FABHA (1-877-443-2242) Questions? Call 1-833-99FABHA (1-833-993-2242)

Complete entire form and fax to Novartis Patient Support at 1-877-44FABHA (1-877-443-2242).

An incomplete Start Form may delay the start of treatment.

424724

FABHALTA (iptacopan) 200 mg capsules

2

- Please fill out all fields on the Start Form to enroll in Novartis Patient Support
- **Sections 1 through 3:** are to be filled out by the patient or their authorized representative
  - Obtain patient and/or authorized representative consent by signature
  - Ensure that your privately insured patient checks the appropriate box in section 2 to sign up for Novartis Patient Support Co-Pay Plus
  - Include front and back copies of patient's prescription insurance cards to allow us to verify all of their benefits
- **Sections 4 through 6:** are to be filled out by the prescriber
  - Make certain that the REMS requirement checkboxes to either ship as soon as possible or hold shipment are checked off in the Vaccination section 5 on page 2
  - Make sure the applicable box is checked for your patient's vaccination support needs in section 5
  - Check that the vaccination information or antibiotic prophylaxis is captured
  - Make sure the box is checked to select your preferred Specialty Pharmacy
  - Select and fill in the appropriate diagnosis code
  - Include whether your patient has taken any other treatments in the past for their current condition in section 6
  - Confirm that the HCP signs and dates the Prescriber Attestation at the bottom of page 2
- An incomplete Start Form may delay the start of treatment

Please see full Important Safety Information and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Novartis Patient Support™

FABHALTA® (iptacopan) START FORM

*** = REQUIRED FIELDS**

Please fill out all fields on this form to enroll in Novartis Patient Support.

1. Patient Information

First Name* | Last Name* | Email

Date of Birth (MM/DD/YYYY)* | Sex for Clinical Use*: ☐ Male ☐ Female | ☐ Mobile ☐ Home Phone Number*‡—*We'll keep you updated through non-marketing calls and texts.*

Address (No PO Box)* | OK to Leave Voicemail: ☐ Yes ☐ No

City | State | ZIP* | Preferred Language: ☐ English ☐ Spanish ☐ Other: _____

I give permission to disclose my personal health information to the following Caregiver (optional):

Caregiver Name | Relationship to Patient

Caregiver Phone Number—*We'll keep you updated through non-marketing calls and texts.*

2. Patient Authorization and Additional Enrollment Consents

I have read and agree to the Patient Authorization on page 3.

X _____ / / _____

Patient/Authorized Representative Signature* | **Date (MM/DD/YYYY)***

☐ Check here if signed by an Authorized Representative.

CO-PAY PLUS§

If you have private insurance, you may be eligible for the $0 Co-Pay Plus Offer by checking the box below.

☐ I have read and agree to the Co-Pay Plus Terms and Conditions on page 3.

ONGOING SUPPORT FROM NOVARTIS PATIENT SUPPORT

You can also get continued one-on-one support from your dedicated Novartis Patient Support Team by checking the box below.

☐ I agree to receive marketing calls and texts from and on behalf of Novartis and its affiliates, including calls and texts made with an autodialer or prerecorded voice, at the phone number(s) I provide. I understand that my consent is not required and is not a condition of receiving any goods or services from Novartis.

3. Insurance Information

To prevent delays, please include copies (front and back) of the patient's prescription insurance card(s). Include primary, secondary, and prescription insurance, if separate from medical insurance.

Check all that apply*: ☐ Primary ☐ Secondary ☐ Prescription ☐ Patient Is Uninsured

4. Prescriber Information

First Name* | Last Name* | Practice Name

Address | Practice Phone Number

City | State | ZIP* | Office Contact Name | Office Contact Phone

Prescriber NPI Number* | Office Fax* | Office Email

Send Fax
1-877-44FABHA (1-877-443-2242)

Questions? Call
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Novartis Patient Support

FABHALTA® (iptacopan) START FORM

5. Vaccination Information

Patient Name* _____ Date of Birth (MM/DD/YYYY)* ___/___/_____

FABHALTA is available through a Risk Evaluation and Mitigation Strategy (REMS) program. Additional information is available by telephone at 1-866-201-3101 or online at www.FABHALTA-REMS.com.

Vaccinate patients against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* (serogroups A, C, W, Y and B), according to current ACIP recommendations at least 2 weeks prior to initiation of FABHALTA. Current ACIP recommendations available at: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

Please select one of the options below and sign the prescriber attestation*:

☐ **SHIP AS SOON AS POSSIBLE—NO PRESCRIBER HOLD**
I have reviewed the FABHALTA vaccination requirements and my patient's vaccination history and certify that vaccinations will be completed OR antibiotic prophylaxis will be prescribed and will be continued until vaccinations have been completed. FABHALTA is authorized to be dispensed as soon as possible.

OR

☐ **HOLD SHIPMENT BUT START INSURANCE PROCESS—PRESCRIBER WILL BE CONTACTED FOR RELEASE**
I have reviewed the FABHALTA vaccination requirements and my patient's vaccination history, and I request that the FABHALTA shipment be held with additional follow-up provided to my office as necessary.

Please mark the checkbox relevant to your patient's vaccination support needs. A dedicated Novartis Patient Support team member will follow up with your patient and provide more information.

☐ My patient requires vaccination support† to help comply with REMS requirements plus other Novartis Patient Support services

☐ My patient requires vaccination support† ***only*** and no other services

Please provide relevant vaccination and antibiotic prophylaxis information for your patient below to support REMS requirements for FABHALTA:

▶ Antibiotic prophylaxis administered? ☐ Yes ☐ No If yes, start date: ___/___/_____ (MM/DD/YYYY)

▶ Vaccines administered? Document the appropriate vaccine type, brand administered, and the administration date (using the MM/DD/YYYY format) of the most recent dose.

MenACWY
1st Dose Date: ___/___/___ ☐ Menveo ☐ Menactra ☐ MenQuadfi
2nd Dose Date: ___/___/___ ☐ Menveo ☐ Menactra ☐ MenQuadfi

MenB
1st Dose Date: ___/___/___ ☐ Bexsero ☐ Trumenba
2nd Dose Date: ___/___/___ ☐ Bexsero ☐ Trumenba
3rd Dose Date: ___/___/___ Only applicable to Trumenba

Pneumococcal
1st Dose Date: ___/___/___ ☐ PCV13 ☐ PCV15 ☐ PCV20 ☐ PPSV23
2nd Dose Date: ___/___/___ ☐ PCV15 ☐ PCV20 ☐ PPSV23 If applicable

6. Prescription Information

Preferred Specialty Pharmacy: ☐ Biologics ☐ CareMed ☐ Onco360 ☐ Other: _____

Primary Diagnosis Code*:

☐ D59.5 Paroxysmal nocturnal hemoglobinuria ☐ N02.B____ (Recurrent and persistent immunoglobulin A nephropathy) ☐ Other: _____

Has your patient previously taken any treatments for their current condition in the past? ☐ Yes ☐ No If yes, please indicate: _____

Pharmacy Prescription:

Product Information	Dosage and Administration	Quantity (60 or 180 capsules)	Refills
FABHALTA 200 mg capsule	200 mg orally twice daily	_____ capsules	☐ 11 refills, or _____ refills

Prescriber Attestation*

Prescriber must authorize these instructions by signing at the end of this section.

I certify the above therapy is medically necessary and this information is accurate to the best of my knowledge. I certify I am the prescriber who has prescribed FABHALTA to the patient named on this form. I certify that any medication received from Novartis Pharmaceuticals Corporation, its affiliates and service providers ("Novartis"), or the Novartis Patient Assistance Foundation, Inc., and its service providers ("NPAF"), will be used only for the patient named on this form and will not be offered for sale, trade, or barter, returned for credit, or submitted for reimbursement in any form. I acknowledge that NPAF is exclusively for purposes of patient care and not for remuneration of any sort. I understand that Novartis and NPAF may revise, change, or terminate their respective programs at any time. I authorize Novartis and NPAF to forward, as my agent, these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies. **I have discussed the Novartis Patient Support Program with my patient, who has authorized me under HIPAA and state law to disclose their information to Novartis for the limited purpose of enrolling in Novartis Patient Support. To complete this enrollment, Novartis may contact the patient by phone, text, and email.**

→ X _____ _____ _____ ___/___/_____

Prescriber Signature (Dispense as Written) **(Substitution Permissible)** **Prescriber Name (Print Name)*** **Date (MM/DD/YYYY)***

ATTN: Please follow your state's prescribing guidelines for electronic prescriptions (if applicable).

Send Fax
1-877-44FABHA (1-877-443-2242)

Questions? Call
1-833-99FABHA (1-833-993-2242)

Complete entire form and fax to Novartis Patient Support at 1-877-44FABHA (1-877-443-2242).

An incomplete Start Form may delay the start of treatment.

Novartis
Patient Support

Patient Authorization

I authorize my healthcare providers, pharmacies and health insurers, and their service providers ("Providers") to disclose information relating to my insurance benefits, medical condition, treatment, and prescription details ("Personal Information") to Novartis Pharmaceuticals Corporation, its affiliates and service providers ("Novartis") and the Novartis Patient Assistance Foundation, Inc., and its service providers ("NPAF") so they can provide the following support services (the "Services"):

- Help coordinate insurance coverage for, access to, and receipt of my medication.
- Communicate with me about possible financial assistance, including Novartis co-pay or NPAF programs, and, if I am enrolled, administer my participation in those programs.
- Communicate with me about my medication and treatment, including reminders, health and lifestyle tips, and product and other related information. Communications may be customized based on Personal Information obtained from my Providers.
- Conduct quality assurance and other internal business activities and ask for feedback related to the Services or my treatment.

In delivering the Services, Novartis and NPAF may share my Personal Information with each other, with my Providers, or with government agencies or other financial assistance programs that might help me pay for my medication. They may combine information collected from me with information collected from other sources and use that information to administer the Services. My pharmacies or other healthcare providers may receive payment from Novartis or NPAF for providing certain Services, such as medication or refill reminders, based on my enrollment or participation. Once I authorize disclosure of my Personal Information, it may no longer be protected by federal health privacy law and applicable state laws.

I understand I do not have to sign this Authorization to get my medication or insurance coverage, that I have a right to a copy, and can cancel this Authorization at any time by calling 1-833-99FABHA (1-833-993-2242) or by writing to:

Novartis Patient Support
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

This Authorization will expire 5 years after I sign it, or earlier if required by state law, unless I cancel it sooner. If I cancel it, I may no longer qualify for Services from Novartis or NPAF, but it will not impact my Provider's treatment or my insurance benefits. I also understand that if a Provider is disclosing my Personal Information to Novartis or NPAF on an authorized, ongoing basis, my cancellation will be effective with respect to that Provider as soon as they receive notice of my cancellation. Cancellation will not affect prior uses or disclosures.

Novartis Patient Support Terms and Conditions

†**Vaccination Support:** Limitations apply. Please contact Novartis Patient Support at 1-833-99FABHA (1-833-993-2242) for more information.

§**Co-Pay Plus:** Limitations apply. Patients with commercial insurance coverage for FABHALTA may receive up to $20,000 in annual co-pay benefits for the cost of FABHALTA and up to $1,000 for qualifying vaccination costs (excluding administrative fees). Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States, Puerto Rico and select territories. Void where prohibited by law. Additional restrictions may apply. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

Bridge Program: Limitations apply. Patients with commercial insurance, a valid prescription for FABHALTA, and a denial of insurance coverage based on a prior authorization requirement may receive a monthly dose for up to 12 months or until insurance coverage approval, whichever occurs first. Not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state program, or where prohibited by law. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional restrictions may apply. Novartis reserves the right to rescind, revoke or amend this Program without notice.

‡Novartis Patient Support may call and text you at the numbers provided for non-marketing purposes (e.g., to help you access and start on FABHALTA). Calls may be autodialed or prerecorded. Message and data rates may apply. You may change your communication preferences at any time by calling 1-833-99FABHA (1-833-993-2242).

Please see full Prescribing Information, including Boxed WARNING and Medication Guide.

Please see the Novartis Pharmaceuticals Corporation Privacy Policy at https://www.novartis.com/us-en/privacy.

Novartis
Patient Support

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

FABHALTA is indicated for:

- The treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- The reduction of 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.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

FABHALTA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life threatening or fatal if not recognized and treated early.

- **Complete or update vaccinations for encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, unless the risks of delaying therapy with FABHALTA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving FABHALTA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the FABHALTA REMS.

CONTRAINDICATIONS

- In patients with serious hypersensitivity to FABHALTA or any of the excipients.
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae* type b.

Novartis
Patient Support

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

- FABHALTA, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis* (caused by any serogroup, including nongroupable strains), 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 is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.

- Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to the start of FABHALTA, according to the current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with FABHALTA. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. 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. The benefits and risks of treatment with FABHALTA, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.

- 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 infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life threatening or fatal if not recognized and treated early. Consider interruption of FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated.

FABHALTA REMS

- FABHALTA is available only through a restricted program under a REMS called FABHALTA REMS, because of the risk of serious infections caused by encapsulated bacteria.

- Under the FABHALTA REMS, prescribers must enroll in the program; counsel patients about the risks, signs, and symptoms of serious infections caused by encapsulated bacteria; provide patients with the REMS educational materials; ensure patients are vaccinated against encapsulated bacteria; prescribe antibacterial drug prophylaxis if patients' vaccine status is not up to date and treatment must be started urgently; and provide instructions to always carry the Patient Safety Card during treatment and for 2 weeks following the last dose of FABHALTA.

- Further information is available by telephone: 1-833-993-2242 or online at www.FABHALTA-REMS.com.

WARNINGS AND PRECAUTIONS (CONTINUED)

Monitoring of PNH Manifestations After FABHALTA Discontinuation

- In PNH patients, after discontinuing FABHALTA, closely monitor patients for at least 2 weeks after the last dose for signs and symptoms of hemolysis. These signs include elevated lactate dehydrogenase (LDH) levels along with a sudden decrease in hemoglobin or PNH clone size, fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (such as thrombosis, stroke, and myocardial infarction), dysphagia, or erectile dysfunction. If discontinuation of FABHALTA is necessary, consider alternative therapy.
- If hemolysis occurs after discontinuation of FABHALTA, consider restarting treatment with FABHALTA, if appropriate, or initiating another treatment for PNH.

Hyperlipidemia

- FABHALTA may increase total cholesterol, LDL cholesterol, and serum triglycerides.
- Of the 88 FABHALTA-treated patients in PNH clinical trials who had normal total cholesterol at baseline, 31 patients developed grade 1 hypercholesterolemia during the randomized or core treatment period, and 1 patient worsened from grade 1 at baseline to grade 2.
- Of the 96 FABHALTA-treated patients in PNH clinical trials with LDL cholesterol ≤130 mg/dL at baseline during the randomized or core treatment period, 14 patients developed LDL cholesterol >130-160 mg/dL, 6 patients developed LDL cholesterol >160-190 mg/dL, and 4 patients developed LDL cholesterol >190 mg/dL.
- Of the 89 FABHALTA-treated patients in PNH clinical trials with normal triglycerides during the randomized or core treatment period, 22 patients developed grade 1 elevated triglycerides. Three patients experienced an increase in triglycerides from grade 1 to grade 2.
- Of the 102 FABHALTA-treated patients in PNH clinical trials, 2 patients required cholesterol-lowering medications.
- Monitor serum lipid parameters periodically during treatment with FABHALTA and initiate cholesterol-lowering medications, if indicated.

ADVERSE REACTIONS

- The most common adverse reactions (≥10%) in adults with PNH receiving FABHALTA were headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, and rash.
- The most common adverse reactions (≥5%) in adults with IgAN receiving FABHALTA were upper respiratory tract infection, lipid disorder, and abdominal pain.

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Patient Support

DRUG INTERACTIONS

- Concomitant use of CYP2C8 inducers (eg, rifampin) may decrease iptacopan exposure, which may result in loss of or reduced efficacy of FABHALTA. Monitor the clinical response and discontinue use of the CYP2C8 inducer if loss of efficacy of FABHALTA is evident.
- Concomitant use of strong CYP2C8 inhibitors (eg, gemfibrozil) may increase iptacopan exposure, which may result in an increased risk for adverse reactions with FABHALTA. Coadministration with a strong CYP2C8 inhibitor is not recommended.

USE IN SPECIFIC POPULATIONS

- Because of the potential for serious adverse reactions in a breastfed child, breastfeeding should be discontinued during treatment and for 5 days after the final dose.
- FABHALTA is not recommended in patients with severe hepatic impairment (Child-Pugh class C). No dose adjustment is required for patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide.

NOVARTIS

FABHALTA® (iptacopan) 200 mg capsules

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