GETTING YOUR PATIENTS STARTED ON FABHALTA

REMS CERTIFICATION

Because of the risk of serious infections caused by encapsulated bacteria, you will need to become certified in the FABHALTA REMS and fulfill its requirements.

Enroll in the FABHALTA REMS:

- **Review** the FABHALTA Prescribing Information and REMS materials
- **Submit** the completed Prescriber Enrollment form to the FABHALTA REMS online at **www.FABHALTA-REMS.com** or by fax to **1-877-206-3255**

After enrollment:

- **Counsel** patients on the risk of serious infections caused by encapsulated bacteria, vaccination requirements, and early signs and symptoms of serious infections
- **Provide** patients with REMS educational materials and the Patient Safety Card
- **Instruct** patients to always carry the card during treatment and for 2 weeks following the last dose of FABHALTA

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.

Additional information is available by telephone at **1-833-99FABHA** or online at **www.FABHALTA-REMS.com**.

VACCINATION AND/OR ANTIBIOTIC PROPHYLAXIS

Comply with the most current ACIP recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.

Required vaccinations: *Streptococcus pneumoniae* and *Neisseria meningitidis* (serogroups A, C, W, Y, and B)

Complete or update vaccines at least 2 weeks before starting FABHALTA, unless the risks of delaying FABHALTA outweigh the risk of developing a serious infection.

If urgent FABHALTA therapy is indicated in a patient who is not up to date with these vaccines:

- **Provide** the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible. For additional details on antibacterial drug prophylaxis, please see the FABHALTA Prescribing Information, Warnings and Precautions (Section 5.1)

During treatment with FABHALTA:

As vaccination does not eliminate the risk of serious encapsulated bacterial infections, closely monitor patients for early signs and symptoms. Inform patients of these signs and symptoms, and instruct patients to seek immediate medical care if they occur.

- **Evaluate** and treat immediately if infection is suspected, as serious infection may rapidly become life threatening or fatal if not recognized and treated early. Promptly treat known infections
- **Consider** interruption of FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment for IgAN
- **While on therapy**, patients are required to be revaccinated as needed

FABHALTA PRESCRIPTION

Prescribing FABHALTA through a limited network of specialty pharmacies

Once you are ready to prescribe FABHALTA, inform your patient which specialty pharmacy in the limited network will be dispensing their FABHALTA prescription.*

Submit Rx by downloading and completing a **Start Form with Novartis Patient Support**, a comprehensive program that offers assistance to health care professionals and patients for getting started on FABHALTA.

- Start Form*: **Fabhalta-startform.com**
- Phone: **1-833-99FABHA**
- Fax: **1-877-44FABHA**

OR

Send the Rx directly to one of the limited network specialty pharmacies.*

CareMed

- Website: **caremedsp.com**
- Phone: **1-877-227-3405**
- Fax: **1-877-542-2731**

Biologics by McKesson

- Website: **biologics.mckesson.com**
- Phone: **1-800-850-4306**
- Fax: **1-800-823-4506**

READY TO GET STARTED?

*Inform your patient which specialty pharmacy will be dispensing their FABHALTA prescription, and tell them to expect a phone call to arrange delivery of their prescription. Pharmacies that dispense FABHALTA must be certified in the FABHALTA REMS and must verify that prescribers are certified.
ACIP, Advisory Committee on Immunization Practices; REMS, Risk Evaluation and Mitigation Strategy.
CareMed, an Onco360 Specialty Pharmacy.

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

NOVARTIS PATIENT SUPPORT™

A dedicated team for you and your patients

Novartis Patient Support is a comprehensive program that can help your eligible patients start and stay on treatment

WE CAN HELP SUPPORT YOU AND YOUR PATIENT THROUGHOUT THEIR JOURNEY WITH THE FOLLOWING:

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

Financial support
Inform your eligible patients about Co-Pay Plus.* Privately insured patients may pay as little as $0 for FABHALTA.

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 can help your patients get started on treatment and support them along the way.

Eligible patients can receive up to 12 months of FABHALTA (iptacopan) for free while coverage is pursued.‡

Novartis Patient Assistance Foundation

The Novartis Patient Assistance Foundation, Inc. (NPAF) is committed to providing access to Novartis medications for those most in need. NPAF may help provide access to Novartis medications for patients who are experiencing financial hardship and/or have no third-party insurance coverage.

To learn more,
Call **1-833-99FABHA (1-833-993-2242)** or visit **www.PAP.Novartis.com**.

Get started with these **two quick links**

ENROLL IN REMS
Visit www.FABHALTA-REMS.com

DOWNLOAD THE START FORM
To submit Rx, visit www.Fabhalta-startform.com

Questions?

For more information on educational resources, call **Novartis Patient Support** at **1-833-99FABHA (1-833-993-2242)**, Monday through Friday, 8:00 AM to 8:00 PM ET.

*__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 toward 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.

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

‡__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 maintenance 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.

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Indication and Important Safety Information

INDICATION

FABHALTA is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

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

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.

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.

ADDITIONAL IMPORTANT SAFETY INFORMATION

Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

Hyperlipidemia

- FABHALTA may increase total cholesterol, LDL cholesterol, and serum triglycerides. Some 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 (≥5%) in adults with IgAN receiving FABHALTA were upper respiratory tract infection, lipid disorder, and abdominal pain.

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 click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

Reference: Fabhalta [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp.

NOVARTIS

FABHALTA® (iptacopan) 200 mg capsules

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

8/24

430649