FABHALTA®
(iptacopan) 200 mg capsules

ONBOARDING GUIDE

Getting started with FABHALTA and available support for you and your patients

Help your patients start their journey with FABHALTA

Enroll in the FABHALTA REMS

Get started with vaccination and antibiotic prophylaxis

Learn about Novartis Patient Support

REMS, Risk Evaluation and Mitigation Strategy.

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

Help your eligible patients start and stay on treatment

This guide provides an overview of the steps needed to help patients begin FABHALTA

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.
- The treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

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.

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FABHALTA REMS[1]

Requirements for REMS certification due to the risk of serious infections caused by encapsulated bacteria

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 REMS

Vaccination and/or antibiotic prophylaxis

Complete or update vaccination against encapsulated bacteria (according to the most current ACIP recommendations for patients receiving a complement inhibitor) at least 2 weeks before starting FABHALTA, unless the risks of delaying FABHALTA outweigh the risk of developing a serious infection.

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

If urgent FABHALTA therapy is indicated in a patient who is not up-to-date with these vaccines, provide antibacterial drug prophylaxis and administer the vaccines according to ACIP recommendations as soon as possible.

Prescription and support

Submit 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.

OR send the Rx directly to CareMed or Biologics by McKesson.*

Novartis Patient Support

Novartis Patient Support (NPS) is a comprehensive program that can help your eligible patients start and stay on treatment.†

DOWNLOAD THE START FORM

*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.

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

ACIP, Advisory Committee on Immunization Practices.

CareMed, an Onco360 Specialty Pharmacy.

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REMS certification[1]

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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.

REMS information and support

- For more information, view the full REMS program details and requirements at **www.FABHALTA-REMS.com**
- For any certification questions, contact the REMS Coordinating Center at **1-833-99FABHA**

REMS certification is a one-time process.

Doctor and patient portrayals.

At all times during your patient's journey, a health care professional should report suspected adverse reactions, including cases of serious bacterial infection, and the patient's clinical outcomes to Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

FDA, US Food and Drug Administration.

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

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REMS certification[1] (continued)

Enrolling in REMS

1. REVIEW

- FABHALTA Prescribing Information
- Health Care Provider Brochure
- Patient Safety Guide
- Patient Safety Card

2. SUBMIT

- Complete Prescriber Enrollment Form at **www.FABHALTA-REMS.com** or fax to **1-877-206-3255**

Once enrolled

3. COUNSEL

- Inform patients about the risk of serious infections caused by encapsulated bacteria, vaccination requirements, and early signs and symptoms of serious infections

4. PROVIDE

- Supply 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

COMPLETE YOUR REMS CERTIFICATION at **www.FABHALTA-REMS.com**

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

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REMS REQUIRED

Vaccination and antibiotic prophylaxis to start treatment[1]

Getting started

It is REQUIRED to complete or update vaccinations at least 2 weeks before starting FABHALTA against:

- ✓ *Streptococcus pneumoniae*
- ✓ *Neisseria meningitidis* (serogroups A, C, W, Y, and B)

Is your patient fully vaccinated?*

YES

Start FABHALTA

NO

Complete required vaccinations, wait at least 2 weeks, then start FABHALTA

If urgent treatment with FABHALTA is required at any point, provide antibiotic prophylaxis + FABHALTA and administer these vaccines as soon as possible

***Patient must wait at least 2 weeks since the last required vaccination dose was administered prior to starting FABHALTA.**
For additional details on antibacterial drug prophylaxis, please see the FABHALTA Prescribing Information, Warnings and Precautions (Section 5.1).

Vaccination support†

Our dedicated Novartis Patient Support team offers support to help your patients locate vaccinations. Call Novartis Patient Support at 1-833-99FABHA (1-833-993-2242) for more information.

See page 11 for more information on vaccination support from Novartis.

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

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

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REMS REQUIRED

Vaccination and antibiotic prophylaxis to start treatment[1] (continued)

During treatment with FABHALTA

1. MONITOR

- As vaccination does not eliminate the risk of serious encapsulated bacterial infections, closely monitor patients for early signs and symptoms

2. INFORM

- Inform patients of these signs and symptoms, and instruct patients to seek immediate medical care if they occur

3. EVALUATE

- **Evaluate and treat immediately if infection is suspected**, as serious infection may become rapidly life-threatening or fatal if not recognized and treated early
- Promptly treat known infections

4. CONSIDER

- It may be necessary to interrupt FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated
- While on therapy, patients are required to be revaccinated as needed

VIEW ACIP GUIDELINES:

Streptococcus pneumoniae

Neisseria meningitidis (serogroups A, C, W, Y, and B)

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ACIP vaccination recommendations

Pneumococcal vaccination in adults with an immunocompromising condition (>19-49 years of age)[2,*]

Required vaccinations while on FABHALTA

Vaccine received at any age	CAPVAXIVE™ (PCV21)		PREVNAR 20® (PCV20)		VAXNEUVANCE® (PCV15)		PNEUMOVAX® 23 (PPSV23)
None/unknown or PREVNAR® (PCV7) only	1 dose	or	1 dose	or	1 dose	and	1 dose at least 8 weeks later[†]
Prior PNEUMOVAX® 23 (PPSV23) only	1 dose at least 1 year since last PNEUMOVAX® 23 (PPSV23)	or	1 dose at least 1 year since last PNEUMOVAX® 23 (PPSV23)	or	1 dose at least 1 year since last PNEUMOVAX® 23 (PPSV23)		-
Prior PREVNAR® 13 (PCV13) only	1 dose	or	1 dose at least 1 year after PREVNAR® 13 (PCV13)		-		-
Prior PREVNAR® 13 (PCV13) + 1 dose of PNEUMOVAX® 23 (PPSV23)[‡]	1 dose at least 5 years after the last pneumococcal vaccine	or	1 dose at least 5 years after the last pneumococcal vaccine		-		-
Prior PREVNAR® 13 (PCV13) + 2 doses of PNEUMOVAX® 23 (PPSV23)[§,‖]	1 dose at least 5 years after the last pneumococcal vaccine	or	1 dose at least 5 years after the last pneumococcal vaccine		-		-

*Review the pneumococcal vaccine recommendations again for patients turning 50 years of age.
[†]For adults who have received PCV15 but have not completed their recommended pneumococcal vaccine series with PPSV23, 1 dose of PCV21 or PCV20 may be used if PPSV23 is not available.
[‡]PPSV23 given at age ≥19 and <65
[§]Received at ≥65 years of age, or 2 doses of PPSV23 for individuals between 19 and 64 years of age.
[‖]Using shared decision-making for adults ≥65 years old.
PCV7, 7-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; PCV15, 15-valent pneumococcal conjugate vaccine; PCV20, 20-valent pneumococcal conjugate vaccine; PCV21, 21-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine.

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ACIP vaccination recommendations (continued)

Meningococcal vaccination in adults with complement deficiencies[3,4,5]

Required vaccinations while on FABHALTA

OPTION 1[3,¶]

PENBRAYA™ (MenACWY-TT/MenB-FHbp)

2 doses
at least 6 months apart

OPTION 2[4,5]

MENACTRA®, MENVEO®, or MENQUADFI® (MenACWY)

2 doses
at least 8 weeks apart

+

BEXSERO® (MenB-4C)

3 doses
at 0, 1 to 2, and 6 months

or

TRUMENBA® (MenB-FHbp)

3 doses
at 0, 1 to 2, and 6 months[#]

Single-dose booster **every 5 years** if the patient is still at increased risk while on FABHALTA

For BEXSERO® or TRUMENBA®, single-dose booster is required **1 year after primary series** and **every 2 to 3 years** thereafter if the patient is still at increased risk while on FABHALTA

Note: BEXSERO® (MenB-4C) and TRUMENBA® (MenB-FHbp) are not interchangeable (use same product for all doses in series).[4]

¶PENBRAYA™ (MenACWY-TT/MenB-FHbp) may be administered to people aged ≥10 years when both a quadravalent meningococcal conjugate vaccine (MenACWY) and meningococcal B vaccine (MenB) are indicated at the same visit. Persons at increased risk for meningococcal disease who have received a dose of PENBRAYA™ (MenACWY-TT/MenB-FHbp) and are recommended to receive additional doses of MenACWY and MenB within 6 months should receive separate MenACWY and MenB-FHbp vaccines, rather than an additional dose of PENBRAYA™ (MenACWY-TT/MenB-FHbp). If PENBRAYA™ (MenACWY-TT/MenB-FHbp) is administered and subsequent doses of MenB are required within 6 months, TRUMENBA® should be administered.[3]

[#]If Dose 2 was administered at least 6 months after Dose 1, then Dose 3 is not needed. If Dose 3 is administered earlier than 4 months after Dose 2, then Dose 4 should be administered at least 4 months after Dose 3.[4]

MenACWY, serogroups A, C, W, and Y meningococcal; MenB, serogroup B meningococcal.

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Prescription and support

Choose one of 2 ways to submit Rx

Complete Start Form with Novartis Patient Support

Please visit

www.Fabhalta-startform.com
to download the **Start Form**

Phone: **1-833-99FABHA**
Fax: **1-877-44FABHA**

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**

OR

Biologics by McKesson

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

*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.
CareMed, an Onco360 Specialty Pharmacy.

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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

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.

Patients with commercial insurance coverage for FABHALTA may receive up to $1,000 for qualifying vaccination costs (excluding administrative fees). Once their insurance coverage is confirmed, your patients can start using their Co-Pay Plus† Card to help cover out-of-pocket costs.

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

Vaccination support

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

- You can opt in to Vaccination Support on the FABHALTA Start Form to further understand what your patient may be eligible for with a dedicated Novartis Patient Support team
- Vaccination Support Terms and Conditions limitations apply. Please contact Novartis Patient Support at **1-833-99FABHA (1-833-993-2242)** Monday through Friday, 8:00 AM-8:00 PM ET, excluding holidays, for more information

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.

†**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.

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

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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.
- The treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

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.

ADDITIONAL IMPORTANT SAFETY INFORMATION

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Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

Serious Infections Caused by Encapsulated Bacteria (continued)

- 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 vaccinations 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' vaccination 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.

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.

ADDITIONAL IMPORTANT SAFETY INFORMATION

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Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

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.
- The most common adverse reactions (≥10%) in adults with C3G receiving FABHALTA were nasopharyngitis and viral infection.

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.

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HELP PATIENTS GET STARTED ON **FABHALTA**[1]

LEARN MORE ABOUT FABHALTA
at **www.Fabhalta-hcp.com**

ENROLL IN REMS
at **www.FABHALTA-REMS.com**

DOWNLOAD THE START FORM
at **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-8:00 PM ET.

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

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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FA-11302836

REFERENCES

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HELP PATIENTS GET STARTED ON **FABHALTA**[1]

References: 1. Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Kobayashi M, Leidner AJ, Gierke R JL, et al. Expanded recommendations for use of pneumococcal conjugate vaccines among adults aged ≥50 years: recommendations of the Advisory Committee on Immunization Practices - United States, 2024. *MMWR Morb Mortal Wkly Rep.* 2025;74(1):1-8. Accessed January 28, 2024. doi:10.15585/mmwr.mm7401a1 **3.** Collins JP, Crowe SJ, Ortega-Sanchez IR, et al. Use of the Pfizer pentavalent meningococcal vaccine among persons aged ≥10 years: recommendations of the Advisory Committee on Immunization Practices - United States, 2023. *MMWR Morb Mortal Wkly Rep.* 2024;73(15):345-350. Accessed January 28, 2024. doi:10.15585/mmwr.mm7315a4 **4.** Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep.* 2020;69(9): 1-41. Accessed October 25, 2024. doi:10.15585/mmwr.rr6909a1 **5.** Schillie S, Loehr J, Chen WH, et al. New dosing interval and schedule for the Bexsero MenB-4C vaccine: updated recommendations of the Advisory Committee on Immunization Practices - United States, October 2024. *MMRW Morb Mortal Wkly Rep.* 2024;73(49):1124-1128.

LEARN MORE ABOUT FABHALTA
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ENROLL IN REMS
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