FABHALTA®
(iptacopan) 200 mg capsules

ONBOARDING GUIDE

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

Doctor and patient portrayals.

INDICATION

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

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

CLICK HERE TO DOWNLOAD AND SUBMIT THE START FORM

Help your patients start their journey with FABHALTA

Get your patients started on FABHALTA with these 3 steps[1]

STEP 1

Getting REMS certified to prescribe FABHALTA

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.

Click here for more details

STEP 2

Complete or update vaccinations before starting treatment with FABHALTA

Complete or update vaccinations for encapsulated bacteria **at least 2 weeks** prior to starting FABHALTA, and readminister during treatment according to the most current ACIP recommendations.

Click here for more details

STEP 3

Prescribing FABHALTA through a limited network of specialty pharmacies

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

Click here for more details

Get started on REMS

Get REMS certified

Novartis Patient Support™

Novartis Patient Support is a comprehensive program that offers assistance to health care professionals and patients for getting started on FABHALTA. **For more information, please click here.**

ACIP, Advisory Committee on Immunization Practices; REMS, Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (continued)
CONTRAINDICATIONS

- 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.

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

Getting REMS certified to prescribe FABHALTA

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 before you can prescribe FABHALTA.[1]

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. These infections may become rapidly life-threatening or fatal if not recognized and treated early. The initiation of FABHALTA is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.[1]

To enroll in the REMS:

Review

the FABHALTA Prescribing Information, Health Care Provider Brochure, Patient Safety Guide, and Patient Safety Card.

Submit

the completed Prescriber Enrollment form to the FABHALTA REMS at www.FABHALTA-REMS.com, or by fax to 1-877-206-3255.

After enrollment[1]:

Counsel

patients about the risk of serious infections caused by encapsulated bacteria, the need for vaccinations, and the early signs and symptoms of serious infections.

Provide

patients with REMS educational materials and the Patient Safety Card. Instruct patients to always carry this card with them during treatment and for 2 weeks following the last dose of FABHALTA.

Get started on REMS

Get REMS certified

At all times during your patient's journey, a health care provider 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.

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.**

IMPORTANT SAFETY INFORMATION (continued)

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.

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

Complete or update vaccinations before starting treatment with FABHALTA

FABHALTA, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria. Comply with the most current ACIP recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.[1]

It is REQUIRED that you vaccinate your patients against[1]:

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

Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to starting FABHALTA, unless the risks of delaying FABHALTA outweigh the risk of developing a serious infection.[1]

- If urgent FABHALTA therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria, 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[1]:

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 receiving treatment for serious infections, depending on the risks of interrupting treatment for PNH
- While on therapy, patients are required to be revaccinated as needed

Required vaccinations before starting FABHALTA
ACIP pneumococcal vaccination recommendations
ACIP meningococcal vaccination recommendations

For more information, refer to the most current ACIP guidelines at www.cdc.gov/acip-recs/hcp/vaccine-specific/.

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.

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

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 years.
[§]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. The brand names mentioned on this page are the property of their respective trademark owners.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Serious Infections Caused by Encapsulated Bacteria (continued)

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.

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

ACIP vaccination recommendations (continued)

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

REQUIRED VACCINATIONS WHILE ON FABHALTA

MENACTRA®, MENVEO®, or MENQUADFI® (MenACWY)[3]		BEXSERO® (MenB-4C)[3,4]		TRUMENBA® (MenB-FHbp)[3]
2 doses at least 8 weeks apart	+	**3 doses at 0, 1 to 2, and 6 months**	or	**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		

PENBRAYA™ (MenACWY-TT/MenB-FHbp) may be administered when MenACWY and MenB vaccinations are indicated at the same visit, provided the patient has not previously received MenB-4C and is not within 6 months of prior PENBRAYA™ vaccination.[5,†]

Note: BEXSERO® (MenB-4C) and TRUMENBA® (MenB-FHbp) are not interchangeable (use same product for all doses in series).[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.[3]
MenACWY, serogroups A, C, W, and Y meningococcal; MenB, serogroup B meningococcal.

†PENBRAYA™ (MenACWY-TT/MenB-FHbp) may be administered to people aged ≥10 years when both a quadrivalent 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.[5]

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Serious Infections Caused by Encapsulated Bacteria (continued)

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.

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

NOVARTIS PATIENT SUPPORT™

A dedicated team for you and your patients

Novartis Patient Support is a comprehensive program that offers assistance to health care professionals and patients for getting started on FABHALTA. Support is available through a dedicated Novartis Patient Support team to help patients starting on FABHALTA.

Novartis Patient Support can help support your eligible patients every step of the way

Insurance support

Financial support

Vaccination support

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

Ongoing support

Vaccination support for your patients getting started on FABHALTA

- Our dedicated Novartis Patient Support team offers support to help your patients locate vaccinations
- You can opt-in to Vaccination Support on the FABHALTA (iptacopan) Start Form to further understand what your patient may be eligible for with a dedicated Novartis Patient Support team
- Vaccination Support T&Cs 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

Novartis Patient Support

Getting started with Novartis Patient Support

Insurance Support and Financial Support

Ongoing Support

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Serious Infections Caused by Encapsulated Bacteria (continued)

- 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.

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

3 steps for getting patients started with Novartis Patient Support

How to enroll:

Download the Start Form at www.fabhalta-hcp.com

Complete the Start Form, capture consent, and submit

Call us at 1-833-99FABHA (1-833-993-2242)

Questions?

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

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. Prescribers must 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 last dose of FABHALTA.

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

Insurance support and financial support

Your dedicated Novartis Patient Support team will work with you to help identify financial support options.

Bridge Program

Your patients may be eligible for up to 12 months of FABHALTA (iptacopan) for free while coverage is pursued.

- 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

Co-Pay Plus

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

- 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

Novartis Patient Support
Getting started with Novartis Patient Support
Insurance Support and Financial Support
Ongoing Support

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
FABHALTA REMS (continued)

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

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

Ongoing support

Novartis Patient Support

Novartis Patient Support provides patients with ongoing help to start, stay, and save on their FABHALTA treatment plan, including:

- Information on financial support options
- Help navigating health care changes
- Tips for setting up a routine that can help patients stay on track with their medication dosing
- Resources about living with PNH, taking FABHALTA, and finding supportive communities
- Support to answer lifestyle questions

Novartis Patient Support
Getting started with Novartis Patient Support
Insurance Support and Financial Support
Ongoing Support

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Monitoring of PNH Manifestations After FABHALTA Discontinuation

- 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 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.

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

Prescribing FABHALTA through a limited network of specialty pharmacies

Once you are ready to prescribe FABHALTA, 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.[1]

Onco360®

- **WEBSITE** onco360.com
- **PHONE** 1-877-662-6633
- **FAX** 1-877-662-6355
- **HOURS OF OPERATION** 24/7

Biologics by McKesson

- **WEBSITE** biologics.mckesson.com
- **PHONE** 1-800-850-4306
- **FAX** 1-800-823-4506
- **HOURS OF OPERATION** 24/7

Novartis does not recommend or require the use of any particular pharmacy.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Hyperlipidemia

- FABHALTA may increase total cholesterol, LDL cholesterol, and serum triglycerides.
- Of 88 FABHALTA-treated patients who had normal total cholesterol at baseline, 31 developed grade 1 hypercholesterolemia during the randomization or core treatment period and 1 patient worsened from baseline grade 1 to grade 2.

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

Indication and Important Safety Information

INDICATION

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

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

- 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.

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. Prescribers must 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 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

- 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 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 88 FABHALTA-treated patients who had normal total cholesterol at baseline, 31 developed grade 1 hypercholesterolemia during the randomization or core treatment period and 1 patient worsened from baseline grade 1 to grade 2.
- Of 96 FABHALTA-treated patients with LDL cholesterol ≤ 130 mg/dL at baseline during the randomization 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 89 FABHALTA-treated patients with normal triglycerides during the randomization 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 APPLY-PNH and APPOINT-PNH, 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.

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 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.

FABHALTA® (iptacopan) 200 mg capsules

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**

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

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