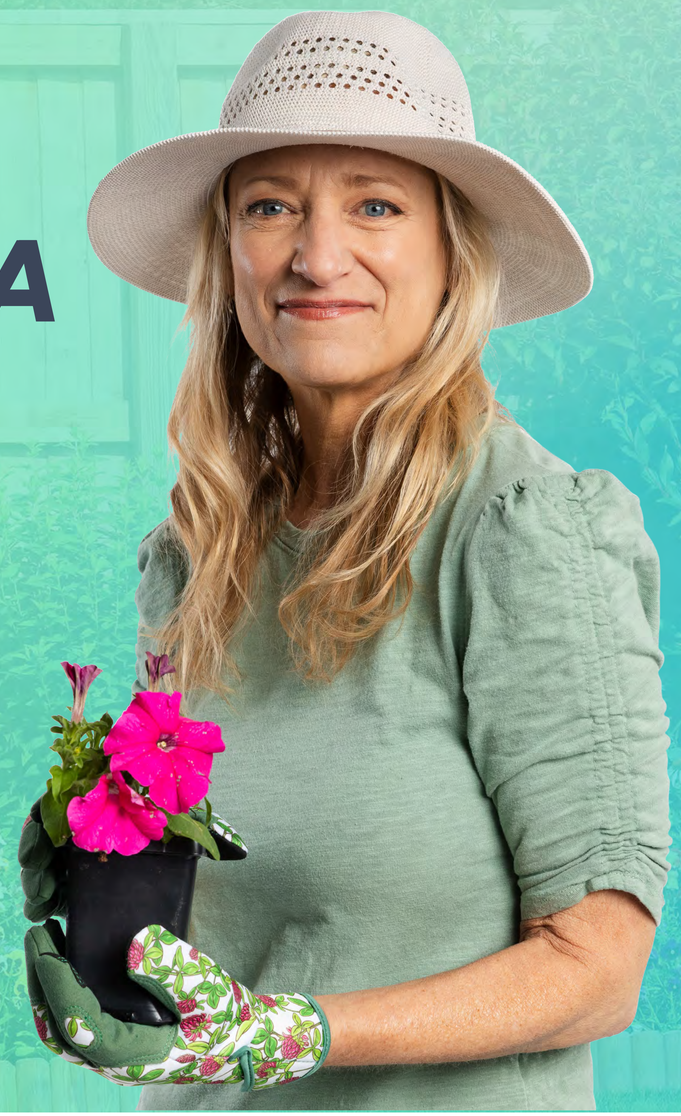
## For Shonda, stability wasn't enough–

# *BUT A SWITCH TO FABHALTA TOOK HER FURTHER*



> *I feel more like myself today on FABHALTA than I have in years.*

**SHONDA, ACTUAL PATIENT TAKING FABHALTA**

COMPENSATED FOR HER TIME BY NOVARTIS. INDIVIDUAL RESULTS MAY VARY.

**FABHALTA®**
**(iptacopan)** 200 mg capsules

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

## An accomplished horticulturist and devoted wife, mother, and grandmother,

# Shonda's celebrating how far she's come with FABHALTA

- ***At the start of her PNH journey, Shonda was a shell of her former self:***
  During the 6 years she spent searching for a diagnosis, Shonda struggled to get through each workday, gradually distancing herself from her loved ones and her favorite activities
- ***Today, Shonda is thriving on FABHALTA and doing what she enjoys:***
  Leading exciting and challenging projects at work, spending time with her family at the lake, and tending to her vibrant garden

## FROM "FINE" TO FABHALTA: SHONDA'S SWITCH FROM A C5i

### Increased Hb levels

Shonda's Hb is now within a **normal range on FABHALTA**.*


Shonda **experienced a 3.2 g/dL increase** in Hb since starting FABHALTA.

### Controlled IVH and EVH

| LDH (U/L) | ARC (M/Cumm) |
|---|---|
| 239§ → 223 | 0.253§ → 0.054 |

These are 2 of the known biomarkers of IVH and EVH.

Unlike C5 inhibitors, **FABHALTA helps to control both of these types of hemolysis**.[1-3]

### Avoided RBC transfusions

Shonda has **not required any RBC transfusions** through 10 months of treatment with FABHALTA.‖

***"Needing transfusions is very scary. So living my life without them up until this point has been incredible."***

### Oral monotherapy

***"I would spend several hours sitting in a treatment center for infusions."***

FABHALTA is the **first and only oral monotherapy for adults with PNH**, freeing Shonda from the burden of infusion center visits.[3]

***"Before diagnosis, life was a struggle. Once I started a C5 inhibitor, I felt better. But on FABHALTA, I feel even better."***

**SHONDA, ACTUAL PATIENT TAKING FABHALTA**

COMPENSATED FOR HER TIME BY NOVARTIS. INDIVIDUAL RESULTS MAY VARY.

*Normal Hb levels vary but generally are between 12-16 g/dL for women and 13-18 g/dL for men.[4]
†Based on patient-reported values as of April 2024.
‡Based on patient-reported values as of March 2025.
§Based on patient-reported values throughout duration of treatment.
‖Based on patient-reported values as of June 2025.

ARC, absolute reticulocyte count; C5i, complement 5 inhibitor; EVH, extravascular hemolysis; Hb, hemoglobin; IVH, intravascular hemolysis; LDH, lactate dehydrogenase; RBC, red blood cell.

## 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.

FABHALTA® (iptacopan) 200 mg capsules

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

**APPLY** A head-to-head study of C5i-experienced (eculizumab or ravulizumab) adults with PNH[3]

# Superior and substantial Hb increases were achieved with FABHALTA over C5is through the 24-week randomized treatment period

**Significantly more patients achieved Hb improvements in the absence of RBC transfusions with FABHALTA vs C5is[1,5]**

PRIMARY END POINTS

## Patients with Hb increase of ≥2 g/dL*

from baseline in the absence of RBC transfusions† after 24 weeks

**RESPONSE RATES**

**82.3%** FABHALTA (n=51/62; 95% CI, 70.5-90.8)

*vs*

**0%** C5is (eculizumab or ravulizumab) (n=0/35; 95% CI, 0-10.0)

(Difference‡: 81.5%; 95% CI, 71.6-91.4; *P*<0.0001)

## Patients with normalized§ Hb of ≥12 g/dL*

in the absence of RBC transfusions† after 24 weeks

**RESPONSE RATES**

**67.7%** FABHALTA (n=42/62; 95% CI, 54.7-79.1)

*vs*

**0%** C5is (eculizumab or ravulizumab) (n=0/35; 95% CI, 0-10.0)

(Difference‡: 66.6%; 95% CI, 54.6-78.6; *P*<0.0001)

APPLY was a 24-week, randomized,‖ open-label, active comparator–controlled, phase 3 trial to assess the efficacy and safety of switching to FABHALTA 200 mg twice daily compared with continuing on intravenous C5i therapy (US-approved and non–US-approved eculizumab or ravulizumab) in adults with PNH and residual anemia (mean Hb <10 g/dL) despite previous treatment with a stable regimen of C5i treatment for at least 6 months; 97 patients were randomized in an 8:5 ratio to either switch to FABHALTA 200 mg taken orally twice daily (n=62) or continue their C5i regimen (n=35: eculizumab, n=23; ravulizumab, n=12). The primary end points in the randomized period were the proportion of patients achieving Hb increase of ≥2 g/dL and the proportion of patients achieving Hb level of ≥12 g/dL,* both without the need for RBC transfusions.[3,5,†]

*Assessed between Days 126 and 168.[3]
†Assessed between Days 14 and 168. Requiring RBCs refers to any patient receiving transfusions or meeting protocol-defined criteria.[5]
‡Adjusted difference in proportion.[3]
§Normalization defined as meeting the primary end point of Hb ≥12 g/dL.[5] Normal Hb levels vary but generally are between 12-16 g/dL for women and 13-18 g/dL for men.[4]
‖Randomization was stratified based on prior C5i treatment and transfusion history within the last 6 months.[3]

**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 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.

FABHALTA® (iptacopan) 200 mg capsules

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

APPLY

A head-to-head study of C5i-experienced (eculizumab or ravulizumab) adults with PNH[3]

# Explore additional data of FABHALTA vs C5is in patients with Hb<10 g/dL after the 24-week randomized treatment period

| ADDITIONAL END POINTS[3,6] | FABHALTA (n=62) | C5is (eculizumab or ravulizumab) (n=35) |
|---|---|---|
| **Adjusted mean change from baseline in ARC*** | **-116 x $10^9$/L** (n=62; 95% CI, -127 to -105) Baseline mean: 193 x$10^9$/L | **0 x $10^9$/L** (n=35; 95% CI, -13 to 14) Baseline mean: 191 x$10^9$/L |
| | Adjusted mean difference: -116 x $10^9$/L; 95% CI, -132 to -100; *P*<0.0001 | |
| The data from this additional analysis are descriptive in nature, presented for observation only. No formal conclusions or comparisons between the 2 treatment arms can be made. | | |
| **Adjusted geometric mean ratio to baseline in LDH†** | **0.96** (n=62) Baseline mean: 269 U/L | **0.97** (n=35) Baseline mean: 273 U/L |
| | No statistically significant difference in LDH was seen between FABHALTA and C5is | |

*Mean change from baseline in ARC ($10^9$/L) assessed between Days 126 and 168. Values include post-transfusion data.[3,6]
†Mean ratio to baseline in LDH assessed between Days 126 and 168.[6]

FABHALTA® (iptacopan) 200 mg capsules

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

**APPLY** A head-to-head study of C5i-experienced (eculizumab or ravulizumab) adults with PNH[3]

# Safety profile of FABHALTA

## ADVERSE REACTIONS WITH FABHALTA (N=62) vs C5is (N=35)[3]

**The adverse reactions reported in >5% of adults with PNH treated with FABHALTA vs C5is in APPLY (24-week randomized treatment period) were:**

- Headache (19% vs 3%)
- Nasopharyngitis (16% vs 17%)
- Diarrhea (15% vs 6%)
- Abdominal pain (15% vs 3%)
- Bacterial infection (11% vs 11%)
- Nausea (10% vs 3%)
- Viral infection (10% vs 31%)
- Arthralgia (8% vs 3%)
- Thrombocytopenia (6% vs 0%)
- Dizziness (6% vs 0%)
- Systemic hypertension (6% vs 0%)
- Lipid disorder (6% vs 0%)

- Serious adverse reactions were reported in 2 (3%) patients with PNH who received FABHALTA. They included pyelonephritis, urinary tract infection, and COVID-19
- Rash was reported in 2 patients (3%)
- Of the 37 FABHALTA-treated patients who had normal platelet counts at baseline, 43% experienced any grade thrombocytopenia during the randomized treatment period
- Three FABHALTA-treated patients experienced decreased platelets that worsened to grade ≥3 from baseline (1 patient with normal platelets that worsened to grade 4; 1 patient with baseline grade 1 that worsened to grade 4; and 1 patient with baseline grade 3 that worsened to grade 4)

**No patient discontinued FABHALTA or C5is due to an adverse reaction during the 24-week randomized treatment period.**
One patient discontinued FABHALTA due to pregnancy[5]

**Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is only available through a REMS program that requires vaccinations.**[3]

Click here for more details.

FABHALTA® (iptacopan) 200 mg capsules

**APPULSE** A study of adults with PNH with Hb ≥10 g/dL who switched from a stable C5i regimen (eculizumab or ravulizumab) to FABHALTA[7]

# Patients with baseline Hb ≥10 g/dL experienced an Hb increase after switching from a C5i to FABHALTA

**The data are for observation only. No formal conclusions can be made.**

PRIMARY END POINT

## Adjusted mean change from baseline in Hb[7,8,*]

**+2.07 g/dL**

(n[†]=51/52) (95% CI, 1.80-2.33)

Mean (SD) baseline Hb levels (g/dL):
11.87 (1.32)

ADDITIONAL END POINT

## Patients with Hb ≥12 g/dL[8]

**92.3%**

(n=48/52[‡]) (95% CI, 81.5-97.9)

Assessed between visits Days 126 and 168
in the absence of RBC transfusions
between Days 1 and 168[§]

APPULSE was a 24-week, single-arm, open-label, multicenter, phase 3b trial to evaluate the efficacy and safety of switching to iptacopan 200 mg twice daily in adults with PNH who had achieved Hb levels ≥10 g/dL[‖] in response to a stable regimen of anti-C5 antibody treatment (eculizumab or ravulizumab) for at least 6 months and had remained transfusion-free during that period. Patients (N=52) were enrolled following an 8-week screening to confirm eligibility, including transfusion history and vaccination status. All received oral iptacopan 200 mg twice daily for 24 weeks.[7]

*Mean of visits between Days 126 and 168 compared with baseline, defined as mean of Hb collected at screening (2 samples) and Day 1. Excludes values within 30 days post-transfusion.[8]
†The 'n' values reflect patients with non-missing values.[8]
‡Percentages are based on the number of subjects with Hb results at that time point.[8]
§Assessed on 3 of 4 measurements taken at the visits occurring in the last 6 weeks.[8]
‖Mean Hb >10 g/L over a period of 6 months before screening visit and confirmed by 2 different samples during the screening period.[7]

**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.

FABHALTA® (iptacopan) 200 mg capsules

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

**APPULSE** A study of adults with PNH with Hb ≥10 g/dL who switched from a stable C5i regimen (eculizumab or ravulizumab) to FABHALTA[7]

# Explore additional data of FABHALTA in patients with Hb ≥10 g/dL after the 24-week treatment period

| ADDITIONAL END POINTS[7,8] | FABHALTA (N=52) |
|---|---|
| The data are for observation only. No formal conclusions can be made. | |
| **Adjusted mean percent change from baseline* in LDH** | **-0.81%** (n†=51; 95% CI, -6.27 to 4.96) Baseline mean: 226.6 U/L |
| **Transfusion avoidance rate‡,§** | **100%** (n=52; 95% CI, 93.2-100.0) |
| **Adjusted mean change from baseline‖ in ARC** | **-90.77 x $10^9$/L** (n†=51; 95% CI, -95.75 to -85.79) Baseline mean: 154.84 x $10^9$/L |

*Percentage change from baseline as mean of visits between Days 126 and 168.[8]
†The 'n' values reflect patients with non-missing values.[8]
‡From 6 months to screening, no transfusions received. In the 12 to 6 months prior to the trial screening period, 3.8% (n=2/52) of patients received a transfusion.[7]
§Transfusion avoidance response rate in APPULSE was defined as absence of administration of packed-RBC transfusions between Days 1 and 168.[7]
‖Change from baseline as mean of visits between Days 126 and 168.[8]

## 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

FABHALTA® (iptacopan) 200 mg capsules

### 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.

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

**APPULSE** A study of adults with PNH with Hb ≥10 g/dL who switched from a stable C5i regimen (eculizumab or ravulizumab) to FABHALTA[7]

# Safety profile of FABHALTA

## ADVERSE REACTIONS WITH FABHALTA[9]

**The adverse reactions reported in >5% of adults with PNH treated with FABHALTA in APPULSE (24-week treatment period) were:**

- Headache (17.3%)
- Nasopharyngitis (17.3%)
- Viral infection (13.5%)
- Diarrhea (11.5%)
- Nausea (11.5%)
- Bacterial infection (9.6%)
- Lipid disorder (7.7%)
- Thrombocytopenia (5.8%)

A serious adverse reaction (bacterial pneumonia) was reported in 1 patient (2%).

ADDITIONAL END POINTS

**The data are for observation only. No formal conclusions can be made.**

**During the 24-week treatment period, no clinical breakthrough hemolysis* or major adverse vascular events (MAVEs)† were observed in patients on FABHALTA[7]**

**One patient discontinued FABHALTA due to an adverse reaction (palpitations)[9]**

*Rate of occurrence through Day 168. Summary measure was occurrences per year.[7]
†The definition of MAVEs included: acute peripheral vascular occlusion, amputation, cerebrovascular accident, cerebral venous occlusion, dermal thrombosis, gangrene, hepatic/portal vein thrombosis, mesenteric/visceral arterial or vein thrombosis or infarction, myocardial infarction, pulmonary embolus, renal arterial or vein thrombosis, thrombophlebitis/deep vein thrombosis, transient ischemic attack, and unstable angina.[7]

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

#### Monitoring of PNH Manifestations After FABHALTA Discontinuation (continued)

- 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.

FABHALTA® (iptacopan) 200 mg capsules

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

# With twice-daily oral dosing, FABHALTA gives your adult patients an option without the need for infusions


## Patients take 1 capsule twice daily[1]

- 200-mg capsule
- FABHALTA can be taken without regard to food
- No refrigeration requirement*
- Patients should swallow capsules whole. Do not open, break, or chew capsules

## Show your patients a world without infusions[1]

- No need to schedule infusion appointments or travel to infusion centers
- No potential for injection-site reactions
- No loading dose or dose adjustment required

## What to do if your patient misses a dose[1]

If a dose or doses are missed, advise your patient to take 1 dose of FABHALTA as soon as possible (even if it is soon before the next scheduled dose) and then to resume the regular dosing schedule.

## Switching from C5is (eculizumab or ravulizumab)[1]

To reduce the potential risk of hemolysis with abrupt discontinuation of other PNH therapies:

- For patients switching from eculizumab, initiate FABHALTA no later than 1 week after the last dose of eculizumab
- For patients switching from ravulizumab, initiate FABHALTA no later than 6 weeks after the last dose of ravulizumab

There is no available information regarding time frame for initiation of FABHALTA after other PNH therapies.

## Drug interactions with FABHALTA[1]

- 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 of FABHALTA in specific populations[1]

Those who are breastfeeding:

- Because of the potential for serious adverse reactions in a breastfed child, breastfeeding should be discontinued during treatment with FABHALTA and for 5 days after the final dose

Those with hepatic impairment:

- 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

*Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted between 15 °C and 30 °C (59 °F and 86 °F).[1]

FABHALTA® (iptacopan) 200 mg capsules

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

- 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.

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

# Help your patients start their journey with FABHALTA

## Get your patients ready with these 3 steps[1]:

### 1 GET 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.

**To enroll in the REMS:**

- ✓ **Review** the FABHALTA Prescribing Information and REMS materials
- ✓ **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:**

- ✓ **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

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**.

### 2 COMPLETE or update vaccinations before starting treatment with FABHALTA

- ✓ **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** vaccinations for encapsulated bacteria at least 2 weeks prior to 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 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:**
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
- While on therapy, patients are required to be revaccinated as needed

### 3 PRESCRIBE FABHALTA through a limited network of specialty pharmacies

- ✓ **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

**Onco360®**

- Website: **onco360.com**
- Phone: 1 (877) 662-6633;
- Fax: 1 (877) 662-6355

**Biologics by McKesson**

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

For more information on how to get your patients started on FABHALTA, please visit **fabhalta-hcp.com/pnh.**

FABHALTA® (iptacopan) 200 mg capsules

**Please click here for full 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.

SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ON THE NEXT PAGE

# 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.

FOR ADULTS WITH PNH

# *EXPLORE THE "FINE" TO FABHALTA SWITCH*

- FABHALTA helps deliver comprehensive hemolysis control (both IVH and EVH)[3]
- FABHALTA is the first and only oral monotherapy approved for adults with PNH[3]
- **Most common adverse reactions in patients taking FABHALTA (incidence ≥10%):** headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, and rash[3]

***"Today, on FABHALTA, I'm finally feeling like myself again, like I have my spark back."***

**SHONDA, ACTUAL PATIENT TAKING FABHALTA**

COMPENSATED FOR HER TIME BY NOVARTIS. INDIVIDUAL RESULTS MAY VARY.

**DISCOVER THE DATA AT FABHALTA-HCP.COM/PNH**

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

**References: 1.** Brodsky RA. Paroxysmal nocturnal hemoglobinuria. *Blood.* 2014;124(18):2804-2811. doi:10.1182/ blood-2014-02-522128 **2.** Risitano AM, Notaro R, Marando L, et al. Complement fraction 3 binding on erythrocytes as additional mechanism of disease in paroxysmal nocturnal hemoglobinuria patients treated by eculizumab. *Blood.* 2009;113(17):4094-4100. doi:10.1182/blood-2008-11-189944 **3.** Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp. **4.** Cappellini MD, Motta I. Anemia in clinical practice—definition and classification: does hemoglobin change with aging? *Semin Hematol.* 2015;52(4):261-269. doi:10.1053/j.seminhematol.2015.07.006 **5.** Data on file. Study CLNP023C12302 CSR. Novartis Pharmaceuticals Corp; 2022. **6.** Data on file. Study CLNP023C12302 and CLNP023C12301 supporting analyses for USPI clinical efficacy section. Novartis Pharmaceuticals Corp; 2023. **7.** Data on file. Study CLNP023C12303 CSR. Novartis Pharmaceuticals Corp; 2024. **8.** Data on file. Study CLNP023C12303 supporting analyses for US Medical deck. Novartis Pharmaceuticals Corp; 2025. **9.** Data on file. Study CLNP023C12303 supporting analysis based on 24-week final safety data. Novartis Pharmaceuticals Corp; 2025.

NOVARTIS

FABHALTA® (iptacopan) 200 mg capsules

**Novartis Pharmaceuticals Corporation**
East Hanover, New Jersey 07936-1080



8/25

FA-11441219