Approved Use

What is FABHALTA?

FABHALTA is a prescription medicine used to treat adults with paroxysmal nocturnal hemoglobinuria (PNH).

It is not known if FABHALTA is safe and effective in children with PNH.

Important Safety Information

What is the most important information I should know about FABHALTA?

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.

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

WHAT COULD HIGHER HEMOGLOBIN (Hb) LEVELS MEAN TO YOU?

Achieving increased Hb levels is an important part of improving your PNH signs and symptoms

Low Hb levels can cause PNH signs like anemia and associated symptoms that can affect your day-to-day activities.

Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men.

"My hemoglobin levels give me insight into how I'm feeling." — A person living with PNH, compensated for their time by Novartis.

When you have PNH, your immune system attacks and destroys red blood cells that lack certain important protective proteins.

This is called hemolysis, and it can result in lower Hb levels.

There are 2 types of hemolysis in PNH:

IVH **(INTRAvascular hemolysis)**
Happens in blood vessels

EVH **(EXTRAvascular hemolysis)**
Happens mostly in liver and spleen

IT'S TIME TO CHANGE YOUR EXPECTATIONS OF WHAT'S POSSIBLE

Reconsider treatment goals and make informed decisions with your care team

PNH can affect your life in ways big and small, whether it's experiencing symptoms or worrying about having to cancel plans. **Even if you are on treatment, you may still feel some signs and symptoms of PNH due to low hemoglobin (Hb) levels.**

A US survey of 122 adults with self-reported PNH showed that patients may remain anemic, fatigued, and require red blood cell (RBC) transfusions despite treatment.

PNH Signs and Symptoms	SOLIRIS® (35 adults)	ULTOMIRIS® (87 adults)
Anemia (Hb <12g/dL)*	**88%** (28 of 32)	**83%** (68 of 82)
RBC transfusions in the past 12 months†	**52%** (12 of 23)	**23%** (7 of 31)
Fatigue‡	**89%** (31 of 35)	**75%** (65 of 87)

In this survey, 97% of adults with PNH (118 of 122) were on SOLIRIS® or ULTOMIRIS® for 3 months or longer. The results may be biased due to other medical conditions reported in these adults, including aplastic anemia in 34% (41 of 122) and bone marrow disorders in less than 6% (7 of 122).

Other potential limitations of the survey were small number of people, higher likelihood of including unsatisfied people (as they may be more motivated to participate), and symptoms based on individuals' own report.

"If your treatment isn't a great fit, don't settle and keep working to find a treatment that's right for you."

— A care partner for someone living with PNH, compensated for their time by Novartis.

Whether you were recently diagnosed or have lived with PNH for years, you should seek out a treatment that can fit your lifestyle.

*Hb data were analyzed for 114 respondents who reported Hb levels.

†Transfusion data are from 54 survey respondents who had received at least one year of SOLIRIS® or ULTOMIRIS® and who had at least one transfusion in their lifetime.

‡People rated their fatigue themselves using FACIT (Functional Assessment of Chronic Illness Therapy)-Fatigue, a 13-item questionnaire used to measure fatigue and its impact on their daily activities and function.

ULTOMIRIS (ravulizumab-cwvz) and SOLIRIS (eculizumab) are registered trademarks of Alexion Pharmaceuticals, Inc.

FABHALTA IS HELPING REDEFINE THE STANDARD FOR PNH TREATMENT

A treatment that can fit your lifestyle

The first and only pill for adults with PNH taken without infusions or injections

Controls both types of hemolysis seen in PNH: intravascular hemolysis (IVH) and extravascular hemolysis (EVH)

4 studies showed how FABHALTA can address common PNH challenges for adults with PNH who had hemoglobin levels of <10 g/dL and ≥10 g/dL

"For the first time since my diagnosis, I feel like there is 'light at the end of the tunnel.' I feel like I am more in control of my PNH instead of it controlling me."

— A person living with PNH, compensated for their time by Novartis. Individual results may vary.

Important Safety Information

What is the most important information I should know about FABHALTA?

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - You must complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of FABHALTA.

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

FABHALTA® (iptacopan) 200 mg capsules

"Since starting FABHALTA, I've been able to focus more on the moments that make me, me, such as spending time with my pets and playing with my child."

— Garrett, a person living with PNH and taking FABHALTA, compensated for his time by Novartis. Individual results may vary.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - If you have not completed your vaccinations and FABHALTA must be started right away, you should receive the required vaccinations as soon as possible.
  - If you have not been vaccinated and FABHALTA must be started right away, you should also receive antibiotics to take for as long as your health care provider tells you.
  - If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.

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

FABHALTA® (iptacopan) 200 mg capsules

4 STUDIES SHOWED HOW FABHALTA CAN ADDRESS COMMON PNH CHALLENGES

The APPLY Study:
A study of adults with PNH who had hemoglobin (Hb) <10 g/dL that compared the effect of switching to FABHALTA from SOLIRIS® (eculizumab) or ULTOMIRIS® (ravulizumab-cwvz).

Learn more on page 7

The APPOINT Study:
A study of adults with PNH who had Hb <10 g/dL and weren't previously treated with a complement inhibitor.

Learn more on page 17

The APPULSE Study:
A study of adults with PNH who had Hb ≥10 g/dL and switched to FABHALTA from SOLIRIS® or ULTOMIRIS®.

Learn more

Those who completed the APPLY or APPOINT studies had the option to continue taking FABHALTA in the 2-Year Long-Term Study.

2-Year Long-Term Study: A long-term study of adults with PNH and Hb <10 g/dL.

Learn more

See how FABHALTA treats your PNH so you can focus on your day-to-day.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - Vaccines do not prevent all infections caused by encapsulated bacteria. **Tell your health care provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
    - Fever with or without shivers or chills
    - Fever with chest pain and cough
    - Fever with high heart rate
    - Headache and fever
    - Confusion
    - Clammy skin
    - Fever and rash
    - Fever with breathlessness or fast breathing
    - Headache with nausea or vomiting
    - Headache with stiff neck or stiff back
    - Body aches with flu-like symptoms
    - Eyes sensitive to light

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

FABHALTA® (iptacopan) 200 mg capsules

THE APPLY STUDY WAS SET UP TO COMPARE THE EFFECT OF SWITCHING TO FABHALTA FROM SOLIRIS® OR ULTOMIRIS®

Who was studied?

97 adults with PNH who had been **on a C5 inhibitor (SOLIRIS® or ULTOMIRIS®) for ≥6 months** before the study and had **hemoglobin (Hb) levels of <10 g/dL**.

What was studied?

The effect of switching to FABHALTA (200 mg pill twice daily) after receiving SOLIRIS® or ULTOMIRIS®.

INITIAL STUDY PERIOD (Weeks 0 to 24)

In the 24-week study:

- 62 adults switched to FABHALTA
- 35 adults remained on SOLIRIS® or ULTOMIRIS® (23 on SOLIRIS® and 12 on ULTOMIRIS®)

The study was primarily set up to understand the percentage of people who had:

- Increased Hb levels by ≥2 g/dL
- Hb levels of ≥12 g/dL*

WITHOUT a need for red blood cell (RBC) transfusions

Additionally, the study looked at:

- Percentage of people who didn't need RBC transfusions
- Changes in Hb levels over time
- Major adverse vascular events, such as stroke, heart attack, or blood clots
- Breakthrough hemolysis† while on treatment
- Self-reported fatigue
- Safety profile

CONTINUED STUDY PERIOD (Weeks 24 to 48)

After the initial study period of 24 weeks, the study continued for an additional 24 weeks:

- 61 of 62 adults continued on FABHALTA
- 34 of 35 adults on SOLIRIS® and ULTOMIRIS® switched to FABHALTA

These were also studied during the continued study period.

*Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men.
†Breakthrough hemolysis was defined as a decrease of ≥2 g/dL in Hb when compared to the latest assessment, or any significant PNH-related signs, symptoms, and other lab criteria.

Important Safety Information *(continued)*

What is the most important information I should know about FABHALTA? (continued)

Your health care provider will give you a Patient Safety Card about the risk of serious infections. Carry it with you at all times during treatment and for 2 weeks after your last dose of FABHALTA. Your risk of serious infections may continue for a few weeks after your last dose of FABHALTA. It is important to show this card to any health care provider who treats you. This will help them diagnose and treat you quickly.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

FABHALTA WAS BETTER AT IMPROVING HEMOGLOBIN (Hb) LEVELS THAN SOLIRIS® OR ULTOMIRIS®

Switching to FABHALTA helped substantially more adults with PNH achieve an Hb increase of ≥2 g/dL without a need for red blood cell (RBC) transfusions

The study was primarily set up to understand the percentage of people who had increased Hb levels by ≥2 g/dL without a need for RBC transfusions.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who had increased Hb levels by ≥2 g/dL without a need for RBC transfusions

82% with **FABHALTA**
51 of 62 people

VS

0% with **SOLIRIS®** or **ULTOMIRIS®**
0 of 35 people

- The average Hb level at the start of the study was 8.9 g/dL for both groups, which is below normal Hb levels
- Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men

"For me, FABHALTA has worked very well. Within a couple of weeks, my hemoglobin had gone up to a normal level and has been stable ever since."

— Kim, a person living with PNH and taking FABHALTA, compensated for her time by Novartis. Individual results may vary.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is only available through a program called the FABHALTA Risk Evaluation and Mitigation Strategy (REMS). Before you can take FABHALTA, your health care provider must:

- Enroll in the FABHALTA REMS program.
- Counsel you about the risk of serious infections caused by certain bacteria.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

FABHALTA HELPED NORMALIZE HEMOGLOBIN (Hb) LEVELS TO ≥12 g/dL

The majority of people who switched to FABHALTA achieved normalized Hb levels of ≥12 g/dL, an important goal in PNH treatment

The study was primarily set up to understand the percentage of people who had normalized Hb levels of ≥12 g/dL without a need for red blood cell (RBC) transfusions.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who had normalized Hb levels of ≥12 g/dL without a need for RBC transfusions

68% with **FABHALTA**
42 of 62 people

VS

0% with **SOLIRIS® or ULTOMIRIS®**
0 of 35 people

- The average Hb level at the start of the study was 8.9 g/dL for both groups, which is below normal Hb levels
- The term "normalized Hb" refers to achieving Hb levels of ≥12 g/dL
- Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men

"Since starting FABHALTA, my hemoglobin is more controlled than with previous treatments."

— Jennifer, a person living with PNH and taking FABHALTA, compensated for her time by Novartis. Individual results may vary.

Increased Hb levels may help improve PNH symptoms due to anemia.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is only available through a program called the FABHALTA Risk Evaluation and Mitigation Strategy (REMS). Before you can take FABHALTA, your health care provider must:

- Give you written information about the symptoms of serious infections.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

FABHALTA ACHIEVED AN INCREASE IN AVERAGE HEMOGLOBIN (Hb) LEVELS

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Average change in Hb from the start of study

+3.6 g/dL with FABHALTA*
62 people

vs

-0.1 g/dL with SOLIRIS® or ULTOMIRIS®
35 people

CONTINUED STUDY PERIOD RESULTS (at Week 48)

People who continued on FABHALTA maintained an increase in Hb levels, and those who switched to FABHALTA at Week 24 increased their Hb levels.

- **3.3 g/dL average increase in Hb levels** at Week 48 compared to the start of the study† for people who continued taking FABHALTA (57 of 62)
- **3.5 g/dL average increase in Hb levels** at Week 48 compared to the start of the study† for people who switched from SOLIRIS® or ULTOMIRIS® to FABHALTA (29 of 35)

*Average was assessed between Weeks 18 and 24. Hb levels within 30 days of a red blood cell (RBC) transfusion were excluded.
†Average was assessed at Week 48. Hb levels within 30 days of an RBC transfusion were excluded.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is only available through a program called the FABHALTA Risk Evaluation and Mitigation Strategy (REMS). Before you can take FABHALTA, your health care provider must:

- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria.
- Make sure you receive antibiotics if you need to start FABHALTA right away and you are not up-to-date on your vaccinations.
- Give you a **Patient Safety Card** about your risk of serious infections.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

FABHALTA HELPED PEOPLE AVOID RED BLOOD CELL (RBC) TRANSFUSIONS

Almost all who switched to FABHALTA did not need RBC transfusions between Weeks 2 and 24

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who didn't need RBC transfusions

95% with FABHALTA
59 of 62 people

VS

46% with SOLIRIS® or ULTOMIRIS®
16 of 35 people

In the 6 months before starting this study:

- 57% of people who switched to FABHALTA from SOLIRIS® or ULTOMIRIS® (35 of 62) had at least one RBC transfusion
- 60% of people who continued on SOLIRIS® or ULTOMIRIS® (21 of 35) had at least one RBC transfusion

*Transfusion avoidance was defined as people who didn't receive RBC transfusions during the specified time period.

CONTINUED STUDY PERIOD RESULTS (at Week 48)

- **92% of people who continued on FABHALTA (57 of 62)** didn't need RBC transfusions between Weeks 2 and 48*
- **94% of people who switched at Week 24 from SOLIRIS® or ULTOMIRIS® to FABHALTA (32 of 34)** didn't need RBC transfusions between Weeks 26 and 48*

"Before I started FABHALTA, I was getting transfused. I knew it could be better."

— Theresa, a person living with PNH and taking FABHALTA, compensated for her time by Novartis. Individual results may vary.

Important Safety Information (continued)

Who should NOT take FABHALTA?

Do not take FABHALTA if you:

- Are allergic to FABHALTA or any of the ingredients in FABHALTA.
- Have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae* type b when you start FABHALTA.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

FATIGUE WAS MEASURED USING A QUESTIONNAIRE

Before the study began and at various points during the study, people rated their fatigue using the **FACIT-Fatigue scale, a 13-item questionnaire used to measure fatigue and its impact on daily activities and function.**

FACIT-Fatigue scores range from 0 to 52

Low scores mean people had MORE FATIGUE

High scores mean people had LESS FATIGUE

In other large-scale surveys not related to this trial, the average FACIT-Fatigue score for the general population was 44.*

*The average FACIT (Functional Assessment of Chronic Illness Therapy)-Fatigue score for the general population was determined in a study of 1010 adults in the United States in 2002 and 2426 adults in Germany in 2018.

Important Safety Information (continued)

Who should NOT take FABHALTA? (continued)

Before you take FABHALTA, tell your health care provider about all your medical conditions, including if you:

- Have an infection or fever.
- Have liver problems.
- Are pregnant or plan to become pregnant. It is not known if FABHALTA will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if FABHALTA passes into your breast milk. You should not breastfeed during treatment and for 5 days after your final dose of FABHALTA.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

FATIGUE WAS STUDIED WITH FABHALTA AND SOLIRIS® OR ULTOMIRIS®

Data from this analysis describe how people reported their fatigue. There are important limitations to the data presented below that you should consider:

- **Because people knew whether they were on FABHALTA or SOLIRIS® or ULTOMIRIS®, they may have under- or over-estimated their fatigue**
- **While on SOLIRIS® or ULTOMIRIS® and before starting FABHALTA, about half the people rated their fatigue as "a little bit" and "not at all" for 10 of the 13 items in the questionnaire**
- **Because of the small number of people in the study (97), the low level of fatigue reported before taking FABHALTA, and since people knew which treatment they were on, it is unknown if these results were due to FABHALTA and no conclusions can be made about the effect of FABHALTA on fatigue**
- **No conclusions or comparisons between FABHALTA and SOLIRIS® or ULTOMIRIS® can be made based on these data**

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Average change in FACIT-Fatigue score at Week 24* compared to the start of the study

+8.6 points with FABHALTA
62 of 62 people

FACIT-Fatigue scores:
43.2 at Week 24 vs 34.7 at start of study

+0.3 points with SOLIRIS® or ULTOMIRIS®
31 of 33 people

FACIT-Fatigue scores:
31.1 at Week 24 vs 30.8 at start of study

CONTINUED STUDY PERIOD RESULTS (at Week 48)

Average change in FACIT-Fatigue score at Week 48 compared to the start of the study

- **+9.8 points** for people who continued on FABHALTA (55 of 62)
- **+10.96 points** for people who switched at Week 24 from SOLIRIS® or ULTOMIRIS® to FABHALTA (26 of 33)

*FACIT-Fatigue score was assessed between Weeks 18 and 24. Values within 30 days after transfusion were included in the analysis.

Important Safety Information (continued)

Who should NOT take FABHALTA? (continued)

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking FABHALTA with certain other medicines may affect the way FABHALTA works and may cause side effects.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your health care provider and pharmacist when you get a new medicine.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

SAFETY PROFILE OF FABHALTA

Adverse reactions reported in more than 5% of adults with PNH treated with FABHALTA during the initial study period (Weeks 0 to 24)

ADVERSE REACTION	FABHALTA (62 adults); n (%)	SOLIRIS® or ULTOMIRIS® (35 adults); n (%)
Headache	12 (19)	1 (3)
Nasal congestion, runny nose, cough, sneezing and sore throat (nasopharyngitis)	10 (16)	6 (17)
Diarrhea	9 (15)	2 (6)
Pain in the stomach (abdomen)	9 (15)	1 (3)
Bacterial infection	7 (11)	4 (11)
Nausea	6 (10)	1 (3)
Viral infection	6 (10)	11 (31)
Joint pain (arthralgia)	5 (8)	1 (3)
Platelet count decreased (thrombocytopenia)	4 (6)	0
Dizziness	4 (6)	0
High blood pressure (systemic hypertension)	4 (6)	0
Cholesterol and/or triglyceride imbalance (lipid disorder)	4 (6)	0

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of FABHALTA.

REMS

Because of the risk of serious infection caused by encapsulated bacteria, FABHALTA is only available through a Risk Evaluation and Mitigation Strategy (REMS) program that requires vaccinations. See page 24 to learn more about the risk of serious infection and the need for vaccinations.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

SAFETY PROFILE OF FABHALTA *(continued)*

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

- Serious adverse reactions (kidney infection, urinary tract infection, and COVID-19) were reported in two people (3%) with PNH receiving FABHALTA
- FABHALTA may increase your cholesterol and triglycerides and your health care provider will do blood tests to check these periodically during treatment
- Rash was reported in two people (3%) taking FABHALTA

CONTINUED STUDY PERIOD RESULTS (at Week 48)

- Serious adverse reactions (deep skin infection caused by bacteria and low platelet levels) were reported in 2% of people on FABHALTA (2 of 96)
- Adverse reactions that occurred in more than 5% of people were viral infection (22.9%), bacterial infection (14.6%, including 6.3% of kidney and urinary infection), nasal congestion, runny nose, cough, sneezing, and sore throat (11.5%), diarrhea (5.2%), headache (5.2%), nausea (5.2%), and low platelet levels (5.2%)

Throughout the 48 weeks of this study, no person discontinued any of the treatments due to adverse reactions. Two people in the study discontinued FABHALTA due to pregnancy.

The study additionally looked at major adverse vascular events (MAVEs) with FABHALTA and SOLIRIS® or ULTOMIRIS®

MAVEs were defined in the study as events involving the blood vessels, such as stroke, heart attack, and blood clots.

This additional analysis is presented for observation only. It is unknown if the following results were due to FABHALTA. We cannot make conclusions from these data, but they are useful to help guide future research.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

1 of 62 people had a MAVE while on FABHALTA

This MAVE (transient ischemic attack, or mini-stroke) was determined to be unrelated to treatment with FABHALTA by the study investigator.

0 of 35 people had a MAVE while on SOLIRIS® or ULTOMIRIS®

CONTINUED STUDY PERIOD RESULTS (at Week 48)

In the overall treatment time through 48 weeks, 3 MAVEs occurred in 3 of 96 people with FABHALTA

- **2 events** occurred between Weeks 1 and 48
- **1 event** occurred after switching from SOLIRIS® or ULTOMIRIS® after Week 24

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO SWITCHED TO FABHALTA

CLINICAL BREAKTHROUGH HEMOLYSIS (BTH) WAS STUDIED WITH FABHALTA AND SOLIRIS® OR ULTOMIRIS®

The study additionally looked at the percentage of people who had intravascular hemolysis, which can still happen while on treatment for PNH. This is BTH, and may result in the need for blood transfusions. In this study, BTH was defined as:

- A decrease of ≥2 g/dL in hemoglobin when compared to the latest assessment, or
- Any significant PNH-related signs, symptoms, and other lab criteria

This additional analysis is presented for observation only. It is unknown if the following results were due to FABHALTA. We cannot make conclusions from these data, but they are useful to help guide future research.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who had BTH

3% with FABHALTA
2 of 62 people

vs

17% with SOLIRIS® or ULTOMIRIS®
6 of 35 people

CONTINUED STUDY PERIOD RESULTS (at Week 48)

In the overall treatment time through 48 weeks, 8 BTH events occurred in 7 of 96 people with FABHALTA

- **7 events** occurred between Weeks 1 and 48
- **1 event** occurred after switching from SOLIRIS® or ULTOMIRIS® after Week 24

Important Safety Information (continued)

Who should NOT take FABHALTA? (continued)

For people with PNH:

- **If you stop taking FABHALTA,** your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. **Stopping FABHALTA may cause a breakdown of red blood cells due to PNH.**

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

FABHALTA® (iptacopan) 200 mg capsules

THE APPOINT STUDY WAS SET UP TO STUDY FABHALTA IN ADULTS WITH PNH WHO WEREN'T PREVIOUSLY TREATED WITH A COMPLEMENT INHIBITOR

Who was studied?

40 adults with PNH who had **hemoglobin (Hb) levels <10 g/dL** as one of the key study criteria.

What was studied?

The effect of FABHALTA (200 mg pill twice daily) on adults with PNH who had **never received a complement inhibitor. FABHALTA was not compared to another treatment in this study.**

INITIAL STUDY PERIOD (Weeks 0 to 24)

The study was primarily set up to understand the percentage of people who had increased Hb levels by ≥2 g/dL without a need for red blood cell (RBC) transfusions.

Additionally, the study looked at:

- Percentage of people who maintained Hb levels of ≥12 g/dL* without a need for RBC transfusions
- Percentage of people who didn't need RBC transfusions
- Major adverse vascular events, such as stroke, heart attack, or blood clots
- Breakthrough hemolysis while on treatment†
- Self-reported fatigue
- Safety profile

CONTINUED STUDY PERIOD (Weeks 24 to 48)

After the initial study period of 24 weeks, the study continued for an additional 24 weeks.

These were also studied in the continued study period.

*Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men.
†Breakthrough hemolysis was defined as a decrease of ≥2 g/dL in Hb when compared to the latest assessment, or any significant PNH-related signs, symptoms, and other lab criteria.

Important Safety Information *(continued)*

Who should NOT take FABHALTA? (continued)

Symptoms or problems that can happen due to breakdown of red blood cells include:

- Decreased hemoglobin level in your blood
- Blood in your urine
- Shortness of breath
- Trouble swallowing
- Tiredness
- Pain in the stomach (abdomen)
- Blood clots, stroke, and heart attack
- Erectile dysfunction

- **It is important you take FABHALTA exactly as your health care provider tells you to lower the possibility of breakdown of red blood cells due to PNH.**

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO WEREN'T PREVIOUSLY TREATED WITH A COMPLEMENT INHIBITOR

FABHALTA HELPED IMPROVE HEMOGLOBIN (Hb) LEVELS

The majority of people on FABHALTA had a meaningful increase in Hb

The study was primarily set up to understand the percentage of people who had increased Hb levels by ≥2 g/dL without a need for red blood cell (RBC) transfusions.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who had increased Hb levels by ≥2 g/dL between Weeks 18 and 24 without a need for RBC transfusions

78% **with FABHALTA**
31 of 40 people

- The average Hb level at the start of the study was 8.2 g/dL, which is below normal Hb levels
- Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men

CONTINUED STUDY PERIOD RESULTS (at Week 48)

93% of people on FABHALTA (37 of 40) had an Hb increase of ≥2 g/dL from the start of the study without a need for RBC transfusions between Weeks 2 and 48.

"I've found that a higher hemoglobin level means that I can do things I didn't do for years, like go to the gym."

— Courtney, a person living with PNH and taking FABHALTA, compensated for her time by Novartis. Individual results may vary.

Important Safety Information (continued)

What are the possible side effects of FABHALTA?

FABHALTA may cause serious side effects, including:

- See **"What is the most important information I should know about FABHALTA?"**
- **Increased cholesterol and triglyceride (lipid) levels in your blood.** Your health care provider will do blood tests to check your cholesterol and triglycerides during treatment with FABHALTA. Your health care provider may start you on a medicine to lower your cholesterol if needed.

The most common side effects of FABHALTA in adults include:

- Headache
- Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)
- Diarrhea
- Feeling dizzy
- Pain in the stomach (abdomen)
- Infections (bacterial and viral)
- Nausea
- Rash

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO WEREN'T PREVIOUSLY TREATED WITH A COMPLEMENT INHIBITOR

THE EFFECT OF FABHALTA ON MAINTAINING HEMOGLOBIN (Hb) LEVELS OF ≥12 g/dL WAS STUDIED

This additional analysis is presented for observation only. It is unknown if the following results were due to FABHALTA. We cannot make conclusions from these data, but they are useful to help guide future research.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who maintained Hb levels of ≥12 g/dL between Weeks 18 and 24 without a need for red blood cell (RBC) transfusions

48% **with FABHALTA**
19 of 40 people

- The average Hb level at the start of the study was 8.2 g/dL, which is below normal Hb levels
- Normal Hb levels vary but are generally between 12-16 g/dL for women and 13-18 g/dL for men

CONTINUED STUDY PERIOD RESULTS (at Week 48)

78% of people on FABHALTA (31 of 40) maintained Hb levels of ≥12 g/dL without a need for RBC transfusions between Weeks 2 and 48.

"Living with PNH, my hemoglobin levels matter to how present I can be in my day-to-day activities."

— Shonda, a person living with PNH and taking FABHALTA, compensated for her time by Novartis. Individual results may vary.

Important Safety Information (continued)

What are the possible side effects of FABHALTA? (continued)

Tell your health care provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of FABHALTA.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO WEREN'T PREVIOUSLY TREATED WITH A COMPLEMENT INHIBITOR

THE NEED FOR RED BLOOD CELL (RBC) TRANSFUSIONS WAS STUDIED

No people on FABHALTA needed RBC transfusions between Weeks 2 and 24 of the study

This additional analysis is presented for observation only. It is unknown if the following results were due to FABHALTA. We cannot make conclusions from these data, but they are useful to help guide future research.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Percentage of people who didn't need RBC transfusions between Weeks 2 and 24

100% **with FABHALTA**
40 of 40 people

In the 6 months before starting this study, 70% of people (28 of 40) needed RBC transfusions.

CONTINUED STUDY PERIOD RESULTS (at Week 48)

98% of people on FABHALTA (39 of 40) did not need RBC transfusions between Weeks 2 and 48.

"That was my goal, to reduce the number of transfusions or not have to get them at all."

— Theresa, a person living with PNH and taking FABHALTA, compensated for her time by Novartis. Individual results may vary.

Important Safety Information

What is the most important information I should know about FABHALTA?

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - You must complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of FABHALTA.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO WEREN'T PREVIOUSLY TREATED WITH A COMPLEMENT INHIBITOR

FATIGUE WAS STUDIED WITH FABHALTA

Before the study began and at various points during the study, people rated their fatigue using the FACIT-Fatigue scale, a 13-item questionnaire used to measure fatigue and its impact on daily activities and function. **FACIT-Fatigue scores range from 0 (worst) to 52 (best), so a higher score means less fatigue.** **See page 12 for a graphic** to help you understand these scores.

In other large-scale surveys not related to this trial, the average FACIT-Fatigue score for the general population was 44.*

Data from this analysis describe how people reported their fatigue. There are important limitations to the data presented below that you should consider:

- **Because people in the trial knew they were on FABHALTA, they may have under- or over-estimated their fatigue**
- **Because of the small number of people in the trial (40) and the fact that people knew the medicine they were taking, it is unknown if these results were due to FABHALTA and no conclusions can be made about the effect of FABHALTA on fatigue**

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

Average change in FACIT-Fatigue score at Week 24† compared to the start of the study

+10.8 points with FABHALTA
40 of 40 people

FACIT-Fatigue scores:
43.9 at Week 24 vs 32.8 at start of study

CONTINUED STUDY PERIOD RESULTS (at Week 48)

Average change in FACIT-Fatigue score at Week 48 compared to the start of the study

- **+10.9 points** for people who continued taking FABHALTA (39 of 40)

*The average FACIT (Functional Assessment of Chronic Illness Therapy)-Fatigue score for the general population was determined in a study of 1010 adults in the United States in 2002 and 2426 adults in Germany in 2018.
†FACIT-Fatigue score was assessed between Weeks 18 and 24.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - If you have not completed your vaccinations and FABHALTA must be started right away, you should receive the required vaccinations as soon as possible.

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

FABHALTA® (iptacopan) 200 mg capsules

SAFETY PROFILE OF FABHALTA

Adverse reactions reported in more than 5% of adults with PNH treated with FABHALTA during the initial study period (Weeks 0 to 24)

ADVERSE REACTION	FABHALTA (40 adults); n (%)
Headache	11 (28)
Viral infection	7 (18)
Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)	6 (15)
Rash	4 (10)
Diarrhea	3 (8)
Pain in the stomach (abdomen)	3 (8)
Cholesterol and/or triglyceride imbalance (lipid disorder)	3 (8)

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of FABHALTA.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)

- Serious adverse reactions (COVID-19 and bacterial pneumonia) were reported in two people (5%) with PNH receiving FABHALTA
- FABHALTA may increase your cholesterol and triglycerides and your health care provider will do blood tests to check these periodically during treatment
- Nausea and bacterial infection were each reported in two people (5%) and dizziness and hives were each reported in one person (3%)

CONTINUED STUDY PERIOD RESULTS (Weeks 24 to 48)

- One serious adverse reaction (COVID-19) was reported in 2.5% (1 of 40) of people on FABHALTA
- Adverse reactions that occurred in more than 5% of people were viral infection (12.5%), nasal congestion, runny nose, cough, sneezing, and sore throat (10%), and diarrhea (7.5%)

Throughout the 48 weeks of this study, no person discontinued FABHALTA due to an adverse reaction.

REMS

Because of the risk of serious infection caused by encapsulated bacteria, FABHALTA is only available through a Risk Evaluation and Mitigation Strategy (REMS) program that requires vaccinations. See page 24 to learn more about the risk of serious infection and the need for vaccinations.

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

FABHALTA® (iptacopan) 200 mg capsules

IN THE STUDY OF ADULTS WITH PNH WHO WEREN'T PREVIOUSLY TREATED WITH A COMPLEMENT INHIBITOR

CLINICAL BREAKTHROUGH HEMOLYSIS (BTH) AND MAJOR ADVERSE VASCULAR EVENTS (MAVEs) WERE STUDIED WITH FABHALTA

The study additionally looked at:

- **The number of people who had intravascular hemolysis, which can still happen while on treatment for PNH. This is BTH, which may result in the need for blood transfusions. In this study, BTH was defined as:**
  - A decrease of ≥2 g/dL in hemoglobin when compared to the latest assessment, or
  - Any significant PNH-related signs, symptoms, and other lab criteria
- **MAVEs, which were defined in the study as events involving the blood vessels, such as stroke, heart attack, and blood clots**

This additional analysis is presented for observation only. It is unknown if the following results were due to FABHALTA. We cannot make conclusions from these data, but they are useful to help guide future research.

INITIAL STUDY PERIOD RESULTS (Weeks 0 to 24)	**CONTINUED STUDY PERIOD RESULTS** (at Week 48)
No one on FABHALTA (0 of 40 people) had a BTH event or MAVE.	• **2 BTH events** occurred in 2 of 40 people treated with FABHALTA • **No one on FABHALTA had a MAVE**

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - If you have not been vaccinated and FABHALTA must be started right away, you should also receive antibiotics to take for as long as your health care provider tells you.

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

FABHALTA® (iptacopan) 200 mg capsules

VACCINATIONS NEEDED BEFORE STARTING FABHALTA

What is the most important information I should know about FABHALTA?

FABHALTA affects part of your immune system and may lower your ability to fight infections

Certain vaccinations help protect you from serious infections while you are taking FABHALTA.

FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria, including *Streptococcus pneumoniae* (pneumonia), *Neisseria meningitidis* (meningitis), and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.

You must complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before starting FABHALTA.

If you have completed your required vaccinations and 2 weeks have passed, you can begin FABHALTA right away.*

If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.

See more information about vaccination requirements, tips, and a complete vaccination checklist.

Vaccines do not prevent all infections caused by encapsulated bacteria.

Tell your health care provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:

- Fever with or without shivers or chills
- Fever with chest pain and cough
- Fever with high heart rate
- Headache and fever
- Confusion
- Clammy skin
- Fever and rash
- Fever with breathlessness or fast breathing
- Headache with nausea or vomiting
- Headache with stiff neck or stiff back
- Body aches with flu-like symptoms
- Eyes sensitive to light

*Some vaccines may require more than one dose, so it's important to know how many doses you need for each vaccine.

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

FABHALTA® (iptacopan) 200 mg capsules

IF YOU HAVE NOT COMPLETED YOUR REQUIRED VACCINATIONS, YOU HAVE 2 OPTIONS

OPTION 1

If you have not completed or updated your vaccinations before starting FABHALTA:

1. Complete or update your required vaccinations
2. Wait at least 2 weeks
3. Begin treatment with FABHALTA

OPTION 2

If FABHALTA needs to be started right away, but you haven't completed or updated your vaccinations, you should:

1. Begin treatment with FABHALTA and antibiotics. You will take these antibiotics for as long as your health care provider tells you
2. Continue to complete or update required vaccinations as soon as possible

Take FABHALTA exactly as your doctor tells you.

While taking FABHALTA, you should be revaccinated according to current medical guidelines for encapsulated bacteria. Your health care provider or Novartis Patient Support can help you locate vaccinations.

The most common side effects of FABHALTA in adults include: headache; nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis); diarrhea; feeling dizzy; pain in the stomach (abdomen); infections (bacterial and viral); nausea; rash.

Tell your health care provider about any side effect that bothers you or that does not go away. These are not all of the possible side effects of FABHALTA.

Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How can I get help obtaining my vaccinations?

Novartis Patient Support (NPS) can provide vaccination support by scheduling an in-home vaccination appointment or helping you find a vaccination location near you.

CLICK HERE

For more on NPS, see page 30.

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

FABHALTA® (iptacopan) 200 mg capsules

THE FABHALTA REMS PROGRAM

Because of the risk of serious infection that comes with taking FABHALTA, it is only available through a restricted program called a Risk Evaluation and Mitigation Strategy (REMS)

Before you can take FABHALTA, your health care provider must:

- Enroll in the FABHALTA REMS program
- Counsel you about the risk of serious infections caused by certain bacteria
- Give you written information about the symptoms of serious infections
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria
- Make sure you receive antibiotics if you need to start FABHALTA right away and you are not up-to-date on your vaccinations
- Give you a **Patient Safety Card** about your risk of serious infections, as discussed below

The FABHALTA Patient Safety Card

Your health care provider will give you a Patient Safety Card about the risk of serious infections. Carry this card with you at all times during treatment and for 2 weeks after your last dose of FABHALTA. Your risk of serious infections may continue for a few weeks after your last dose of FABHALTA. It is important to show this card to any health care provider who treats you. This will help them diagnose and treat you quickly.

If you notice any signs or symptoms described on this card, contact your doctor or get emergency medical assistance immediately.

DID YOU KNOW? REMS programs are used for a number of drugs and are meant to protect your health.

Important Safety Information (continued)

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.

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

FABHALTA® (iptacopan) 200 mg capsules

TAKE FABHALTA AT HOME OR ON THE GO

One pill, twice a day, every day

- With or without food
- Swallow the pills whole. Do not open, break, or chew pills
- You do not need to refrigerate FABHALTA*

If you miss your FABHALTA dose or doses:

- As soon as you remember, take one dose of FABHALTA, even if it is almost time to take your next scheduled dose
- Then take your next dose of FABHALTA at your regularly scheduled time

Take FABHALTA exactly as your doctor tells you. Do not change the dose or stop taking FABHALTA unless your doctor tells you.

*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).

What you need to know about switching to FABHALTA

- **For people switching from ULTOMIRIS®:** start taking FABHALTA no later than 6 weeks after the last dose
- **For people switching from SOLIRIS®:** start taking FABHALTA no later than 1 week after the last dose

If you stop taking FABHALTA

- Your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA
- Stopping FABHALTA may cause a breakdown of red blood cells due to PNH
- Symptoms or problems that can happen due to breakdown of red blood cells include:
  - Decreased hemoglobin level in your blood
  - Blood in your urine
  - Shortness of breath
  - Trouble swallowing
  - Tiredness
  - Pain in the stomach (abdomen)
  - Blood clots, stroke, and heart attack
  - Erectile dysfunction
- **It is important you take FABHALTA exactly as your health care provider tells you to lower the possibility of breakdown of red blood cells due to PNH**

Important Safety Information *(continued)*

What is the most important information I should know about FABHALTA? (continued)

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - Vaccines do not prevent all infections caused by encapsulated bacteria. **Tell your health care provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
    - Fever with or without shivers or chills
    - Fever with chest pain and cough
    - Fever with high heart rate
    - Headache and fever
    - Confusion
    - Clammy skin
    - Fever and rash
    - Fever with breathlessness or fast breathing
    - Headache with nausea or vomiting
    - Headache with stiff neck or stiff back
    - Body aches with flu-like symptoms
    - Eyes sensitive to light

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

FABHALTA® (iptacopan) 200 mg capsules

IMPORTANT FACTS ABOUT FABHALTA *(iptacopan)*

What is FABHALTA?

FABHALTA is a prescription medicine used to treat adults with paroxysmal nocturnal hemoglobinuria (PNH).

It is not known if FABHALTA is safe and effective in children with PNH.

Important Safety Information

What is the most important information I should know about FABHALTA?

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
  - You must complete or update your vaccinations against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of FABHALTA.
  - If you have not completed your vaccinations and FABHALTA must be started right away, you should receive the required vaccinations as soon as possible.
  - If you have not been vaccinated and FABHALTA must be started right away, you should also receive antibiotics to take for as long as your health care provider tells you.
  - If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting FABHALTA. Your health care provider will decide if you need additional vaccinations.
  - Vaccines do not prevent all infections caused by encapsulated bacteria. **Tell your health care provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
    - Fever with or without shivers or chills
    - Fever with chest pain and cough
    - Fever with high heart rate
    - Headache and fever
    - Confusion
    - Clammy skin
    - Fever and rash
    - Fever with breathlessness or fast breathing
    - Headache with nausea or vomiting
    - Headache with stiff neck or stiff back
    - Body aches with flu-like symptoms
    - Eyes sensitive to light

Your health care provider will give you a Patient Safety Card about the risk of serious infections. Carry it with you at all times during treatment and for 2 weeks after your last dose of FABHALTA. Your risk of serious infections may continue for a few weeks after your last dose of FABHALTA. It is important to show this card to any health care provider who treats you. This will help them diagnose and treat you quickly.

FABHALTA is only available through a program called the FABHALTA Risk Evaluation and Mitigation Strategy (REMS). Before you can take FABHALTA, your health care provider must:

- Enroll in the FABHALTA REMS program.
- Counsel you about the risk of serious infections caused by certain bacteria.
- Give you written information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria.
- Make sure you receive antibiotics if you need to start FABHALTA right away and you are not up-to-date on your vaccinations.
- Give you a **Patient Safety Card** about your risk of serious infections.

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

FABHALTA® (iptacopan) 200 mg capsules

IMPORTANT SAFETY INFORMATION *(continued)*

Who should NOT take FABHALTA?

Do not take FABHALTA if you:

- Are allergic to FABHALTA or any of the ingredients in FABHALTA.
- Have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis*, or *Haemophilus influenzae* type b when you start FABHALTA.

Before you take FABHALTA, tell your health care provider about all your medical conditions, including if you:

- Have an infection or fever.
- Have liver problems.
- Are pregnant or plan to become pregnant. It is not known if FABHALTA will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if FABHALTA passes into your breast milk. You should not breastfeed during treatment and for 5 days after your final dose of FABHALTA.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking FABHALTA with certain other medicines may affect the way FABHALTA works and may cause side effects.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your health care provider and pharmacist when you get a new medicine.

For people with PNH:

- **If you stop taking FABHALTA,** your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. **Stopping FABHALTA may cause a breakdown of red blood cells due to PNH.**

  Symptoms or problems that can happen due to breakdown of red blood cells include:

  - Decreased hemoglobin level in your blood
  - Blood in your urine
  - Shortness of breath
  - Trouble swallowing
  - Tiredness
  - Pain in the stomach (abdomen)
  - Blood clots, stroke, and heart attack
  - Erectile dysfunction

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

- **It is important you take FABHALTA exactly as your health care provider tells you to lower the possibility of breakdown of red blood cells due to PNH.**

What are the possible side effects of FABHALTA?

FABHALTA may cause serious side effects, including:

- See **"What is the most important information I should know about FABHALTA?"**
- **Increased cholesterol and triglyceride (lipid) levels in your blood.** Your health care provider will do blood tests to check your cholesterol and triglycerides during treatment with FABHALTA. Your health care provider may start you on a medicine to lower your cholesterol if needed.

The most common side effects of FABHALTA in adults include:

- Headache
- Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)
- Diarrhea
- Feeling dizzy
- Pain in the stomach (abdomen)
- Infections (bacterial and viral)
- Nausea
- Rash

Tell your health care provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of FABHALTA.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This information is not comprehensive

How to get more information: Talk to your health care provider or visit www.FABHALTA.com to obtain the FDA-approved product labeling.

FABHALTA® (iptacopan) 200 mg capsules

NOVARTIS PATIENT SUPPORT CAN HELP YOU EVERY STEP OF THE WAY

Personalized support that can help you start, stay, and save on treatment

Once you've been prescribed FABHALTA, you or your loved one can sign up for **Novartis Patient Support**™. It's a comprehensive program with a dedicated team in your corner.

You'll have a go-to team member who will reach out from the start and get to know you. When you have questions, you can talk to them directly.*

Insurance support
Navigate the insurance process and understand your insurance coverage information.

Financial support
Learn about savings and other possible ways to afford your treatment.

Vaccination support
Get help scheduling in-home vaccination appointments, finding vaccination locations near you, or guidance on accessing existing vaccination records.

Ongoing support
Get helpful resources and answers to your questions throughout your treatment.

FINANCIAL SUPPORT

Learn about the $0 Co-Pay Plus offer and the FABHALTA Bridge Program on the next page. Also see terms and conditions indicated with footnote symbols on the next page.

Sign up for Novartis Patient Support

There are a few different ways to start getting support:

1. **Call 833-99FABHA (833-993-2242)**, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays. Your dedicated Novartis Patient Support team can then help you sign up
2. **Click here** to sign up online
3. **Ask your health care provider** to help sign you up at your next appointment

*Novartis Patient Support does not provide clinical advice and is not a substitute for consulting with your health care provider.

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

FABHALTA® (iptacopan) 200 mg capsules

NOVARTIS PATIENT SUPPORT: FINANCIAL SUPPORT

Novartis Patient Support™

$0 Co-Pay Plus* offer

If you have private insurance, you may be eligible for the $0 Co-Pay Plus offer for FABHALTA through Novartis Patient Support.

Start FABHALTA at no cost, if you're eligible

With the FABHALTA Bridge Program, if you are privately insured and eligible, you can get up to 12 months of FABHALTA for free while insurance coverage is pursued.†

To enroll in Co-Pay Plus,* click here

You may also enroll in Co-Pay Plus* by calling 833-99FABHA (833-993-2242).

***Limitations apply.** Patients with private 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 the 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 this Program and discontinue support at any time without notice.

†**The Bridge Program applies to FABHALTA only.** Eligible patients must have private insurance and a valid prescription for FABHALTA, and a prior authorization or an initial denial of coverage. Program requires the submission of a prior authorization or an appeal of the coverage denial within the first 45 days of enrollment to remain eligible. Program provides FABHALTA for free to eligible patients for up to 12 months, or until they receive insurance coverage approval, whichever occurs earlier. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Patients may be asked to reverify insurance coverage status during the course of the Program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional limitations may apply. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this Program without notice.

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

FABHALTA® (iptacopan) 200 mg capsules

EXPECT MORE FROM YOUR PNH TREATMENT

- **The first and only pill for adults with PNH taken without infusions or injections**
- **Controls both types of hemolysis seen in PNH: intravascular hemolysis (IVH) and extravascular hemolysis (EVH)**
- **4 studies showed how FABHALTA can address common PNH challenges for adults with PNH who had hemoglobin levels of <10 g/dL and ≥10 g/dL**

Take control of your PNH journey. Talk to your doctor about FABHALTA.

Find useful resources and hear from people who have gone from "fine" to FABHALTA.

Approved Use

What is FABHALTA?

FABHALTA is a prescription medicine used to treat adults with paroxysmal nocturnal hemoglobinuria (PNH).

It is not known if FABHALTA is safe and effective in children with PNH.

Important Safety Information

What is the most important information I should know about FABHALTA?

FABHALTA is a medicine that affects part of your immune system and may lower your ability to fight infections.

- **FABHALTA increases your chance of getting serious infections caused by encapsulated bacteria,** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.

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

NOVARTIS

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FA-11753561

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