Patient portrayal.

FABHALTA® (iptacopan) 200 mg capsules

Ask your doctor about FABHALTA, a groundbreaking, FDA-approved oral PNH treatment for adults

Improved hemoglobin (Hb) levels with the first FDA-approved oral treatment for adults with PNH. In a study of 62 people receiving FABHALTA and 35 people receiving C5 inhibitors, 82% of people taking FABHALTA had an increase in Hb ≥2 g/dL vs 0% of people taking C5 inhibitors. 68% of people taking FABHALTA had Hb levels ≥12 g/dL vs 0% of people taking C5 inhibitors. These results were achieved in the absence of red blood cell transfusions after 24 weeks.

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.

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 fatal if not recognized and treated early.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

PNH WREAKS HAVOC ON RED BLOOD CELLS

PNH, or paroxysmal nocturnal hemoglobinuria, is a rare disease caused by a bone marrow defect. Due to this, red blood cells lack certain important protective proteins.

What happens to red blood cells that lack certain protective proteins (CD55 and CD59)?

When your red blood cells lack protection, they can be left vulnerable and mistakenly attacked by the immune system. This is called hemolysis.

IVH

EVH

There are two types of hemolysis in PNH:

- Intravascular hemolysis (IVH), which happens in your blood vessels
- Extravascular hemolysis (EVH), which happens most commonly in your liver and spleen

Hb

In PNH, as red blood cells are destroyed, hemoglobin levels decline.

Hemoglobin is an important protein found in the blood that carries oxygen throughout your body.

Patient portrayal.

PNH CAN HAVE A SIGNIFICANT IMPACT

The signs and symptoms of PNH may vary and can impact how you feel on a daily basis.

It can impact how you feel physically and emotionally

It can affect how you function day to day

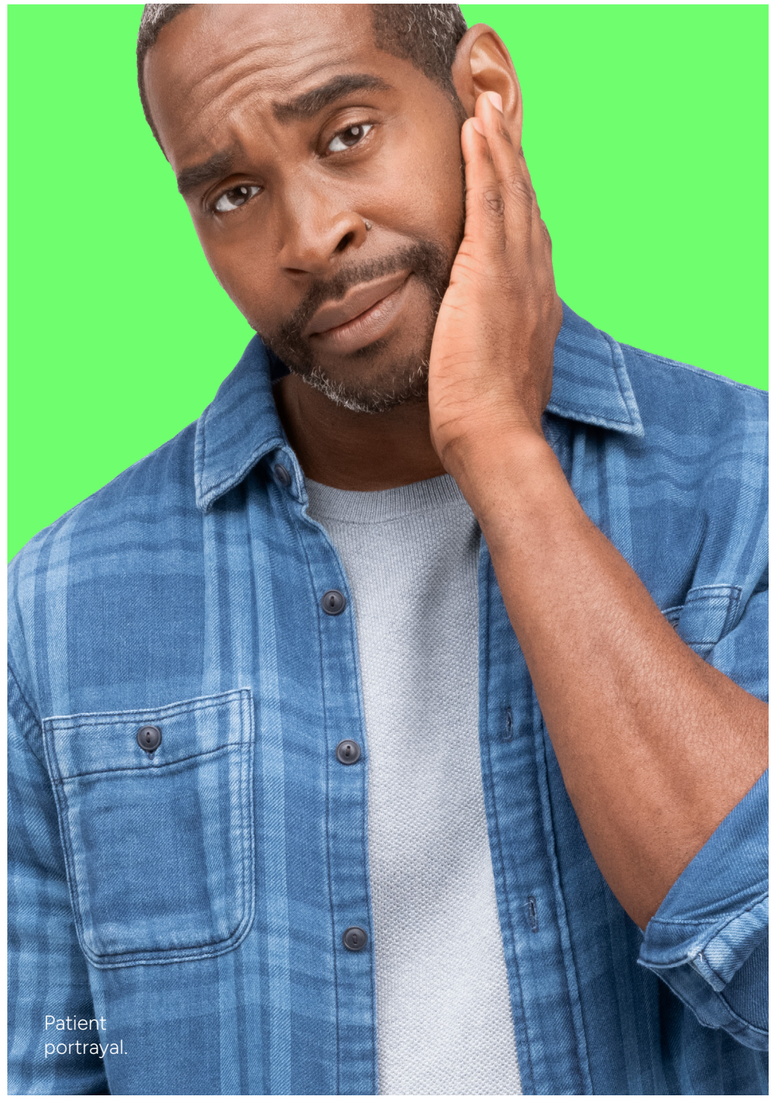
"I have had to adjust my expectations for myself and have to ask for help more than I would like and more than I used to."

— Person living with PNH

"I would describe my PNH as unpredictable. I can't say from day to day how I am going to feel when I wake up in the morning."

— Person living with PNH

People quoted above were compensated for their time during interviews.



FABHALTA WAS STUDIED TO SEE HOW IT COULD

IMPACT SOME OF THE MOST COMMON CHALLENGES OF PNH

Hemoglobin levels

Percent of people who:

- Had an increase of hemoglobin levels ≥2 g/dL
- Reached a hemoglobin level ≥12 g/dL

Without the need for a red blood cell (RBC) transfusion

RBC transfusions

Percent of people who did not receive an RBC transfusion during the clinical trials

Doctor portrayal.

The studies also looked at:

- Changes in hemoglobin levels over time
- The rate of occurrence of major adverse vascular events involving the blood vessels, such as stroke, heart attack, or blood clots
- The rate of clinical breakthrough hemolysis (in which a person experiences a decrease of ≥2 g/dL in hemoglobin compared to the last assessment or within 15 days, or other significant increase in PNH-related signs or symptoms)

Important Safety Information (continued)

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

- 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 therapy 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.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

FABHALTA WAS STUDIED IN ADULTS WITH PNH

C5 Inhibitor-Experienced Adults With PNH

What was studied?

APPLY was a 24-week study of adults with PNH. It was meant to study the impact on people who switched to FABHALTA or continued on their C5 inhibitor (SOLIRIS® or ULTOMIRIS®).

Who was studied?

All 97 participants in APPLY were already on a C5 inhibitor for at least 6 months before the study and had hemoglobin levels below 10 g/dL as one of the key study criteria.

How was the study done?

Results were compared between 62 adults taking 200 mg of FABHALTA twice daily and 35 adults who remained on their C5 inhibitor (23 on SOLIRIS® and 12 on ULTOMIRIS®).

SEE THE RESULTS »

Complement Inhibitor-Naive Adults With PNH

What was studied?

APPOINT was a 24-week study of FABHALTA in adults with PNH. It was meant to see the impact of FABHALTA on people who had never taken a complement inhibitor treatment before.

Who was studied?

All 40 participants in APPOINT had hemoglobin levels below 10 g/dL as one of the key study criteria.

How was the study done?

Results measured the impact of taking 200 mg of FABHALTA twice daily in 40 adults. In this trial, FABHALTA was not compared to another treatment.

SEE THE RESULTS »

What is a C5 inhibitor?

C5 inhibitors, or C5i for short, are a category of treatments that include SOLIRIS and ULTOMIRIS that are used to treat people with PNH.

Important Safety Information (continued)

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

- 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 the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

A DIFFERENT WAY TO HELP IMPROVE HEMOGLOBIN LEVELS

Primary study objective:

Hemoglobin increased by 2 or more g/dL in absence of red blood cell transfusions

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

VS

0% *with* **C5 INHIBITORS**
(SOLIRIS® [eculizumab] or ULTOMIRIS® [ravulizumab-cwvz])
0 out of 35 people

- Data were assessed **after 24 weeks**
- After 24 weeks, FABHALTA increased hemoglobin levels by an average of **3.6 g/dL** vs the average decrease of **0.1 g/dL** with C5 inhibitors (SOLIRIS or ULTOMIRIS). The average starting hemoglobin level prior to treatment was 8.9 g/dL for both groups

Important Safety Information (continued)

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

- Vaccines do not prevent all infections caused by encapsulated bacteria. **Call your health care provider or get emergency medical care right away if you have 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 a 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 the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

HIGHER HEMOGLOBIN LEVELS ARE POSSIBLE

Primary study objective:

The majority of people taking FABHALTA achieved normalized hemoglobin levels of ≥12 g/dL without the need for RBC transfusions after 24 weeks

Hb

68% *with* **FABHALTA**

42 out of 62 people

VS

0% *with* **C5 INHIBITORS**

(SOLIRIS® [eculizumab] or ULTOMIRIS® [ravulizumab-cwvz])

0 out of 35 people

- The average starting hemoglobin level prior to treatment was 8.9 g/dL for both groups

What does normalized hemoglobin mean?

The term normalized hemoglobin refers to achieving Hb levels ≥12 g/dL. Normal hemoglobin levels vary, but are generally between 12-16 g/dL for women and 13-18 g/dL for men.

Patient portrayal.

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 the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

LESS NEED FOR RED BLOOD CELL TRANSFUSIONS

Almost all who switched to FABHALTA did not receive an RBC transfusion

RBC transfusion avoidance assessed between Weeks 2 and 24

95%
FABHALTA
59 out of 62 people

vs

46%
C5 INHIBITORS
(SOLIRIS® [eculizumab] or ULTOMIRIS® [ravulizumab-cwvz])
16 out of 35 people

In the 6 months before the trial:

- 57% (n=35/62) of people in the FABHALTA group had at least one RBC transfusion
- 60% (n=21/35) of people in the C5i group had at least one RBC transfusion

What is transfusion avoidance?

Transfusion avoidance means people did not receive transfusions during the assessed time period between Weeks 2 and 24.

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.
- Give you information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that 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 the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

SAFETY PROFILE OF FABHALTA

Adverse reactions reported in >5% of adults with PNH treated with FABHALTA (24-week treatment period)

ADVERSE REACTION	**FABHALTA** (N=62); n (%)	**C5i** (N=35); n (%) SOLIRIS (eculizumab) or ULTOMIRIS (ravulizumab)
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

- 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 them periodically during treatment
- Rash was reported in two people (3%) taking FABHALTA
- **No patient discontinued FABHALTA or a C5i due to an adverse reaction during the 24-week clinical trial.** One patient in the clinical trial discontinued FABHALTA due to pregnancy

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 14 to learn more about the risk of serious infection and the need for vaccinations.

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.

HELP IMPROVE HEMOGLOBIN LEVELS

Primary study objective:

Hemoglobin increased by 2 g/dL or more in the absence of red blood cell transfusions

78%

31 out of the 40 people who started on FABHALTA showed an increase in hemoglobin level of 2 g/dL or more without a red blood cell transfusion

- The average starting hemoglobin level prior to treatment was 8.2 g/dL
- Hemoglobin increases were assessed between Week 18 and Week 24
- Data based on Hb values from central laboratory

Additional analysis

88%

35 out of 40 people

While the data on the primary analysis (78%) is based on central laboratory values (primary laboratory designated for this study), the additional analysis shown above includes 4 additional people out of 40 total people in the study who achieved the result but were unable to travel to the central laboratory for testing and were tested at a local laboratory instead.


Patient portrayal.

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 are starting FABHALTA.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

HEMOGLOBIN LEVELS

Percent of people on FABHALTA who reached a hemoglobin level of ≥12 g/dL in the absence of RBC transfusions

The data from this additional analysis are exploratory and presented for observation only. It is unknown if the following results were due to FABHALTA or not. We cannot make conclusions from exploratory data, but it is useful to help guide future research.

Hb

48%

19 out of 40 people who started on FABHALTA reached a hemoglobin level of 12 g/dL or more without a red blood cell transfusion

- The average starting hemoglobin level prior to treatment was 8.2 g/dL
- Hemoglobin levels ≥12 g/dL were assessed between Week 18 and Week 24

What is considered a "normal" hemoglobin level?

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

Important Safety Information (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.

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 the Summary of Important Information on pages 17–18.

RED BLOOD CELL TRANSFUSIONS WITH FABHALTA

Percent of people on FABHALTA who did not receive a red blood cell transfusion between Weeks 2 and 24 of the clinical trial

The data from this additional analysis are exploratory and presented for observation only. It is unknown if the following results were due to FABHALTA or not. We cannot make conclusions from exploratory data, but it is useful to help guide future research.

RBC transfusion avoidance assessed between Weeks 2 and 24

100%

FABHALTA

40 out of 40 people

28 of 40 people (70%) required an RBC transfusion in the 6 months before starting the trial

What is transfusion avoidance?

Transfusion avoidance means people did not receive transfusions during the assessed time period between Weeks 2 and 24.

Important Safety Information (continued)

If you have PNH and you stop taking FABHALTA, your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. **Stopping treatment with 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 (ED)

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 the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

SAFETY PROFILE OF FABHALTA

Adverse reactions reported in >5% of adult people treated with FABHALTA (24-week treatment period)

ADVERSE REACTION	FABHALTA (N=40); 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)

- 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 them 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%)

No patient discontinued FABHALTA due to an adverse reaction in the 24 week clinical trial.

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 14 to learn more about the risk of serious infection and the need for vaccinations.

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.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

SERIOUS RISK OF INFECTIONS AND VACCINES

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 fatal if not recognized and treated early.

- You must 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.

While taking FABHALTA, you should be revaccinated according to current medical guidelines for encapsulated bacteria.

View the most common adverse reactions seen with FABHALTA in C5 inhibitor-experienced people.
CLICK HERE

View the most common adverse reactions seen with FABHALTA in complement-inhibitor naive people.
CLICK HERE

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.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

Vaccines do not prevent all infections caused by encapsulated bacteria.

Call your health care provider or get emergency medical care right away if you have 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 a 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

FABHALTA® (iptacopan) 200 mg capsules

THE FABHALTA REMS PROGRAM

Because of the risk of serious infection that comes with taking FABHALTA, it's only available through a restricted program called 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 information about the symptoms of serious infections
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that 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

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To learn more about the FABHALTA REMS program, please call the REMS helpline at **1-833-99FABHA (1-833-993-2242)** Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays, or visit **www.Fabhalta-REMS.com** today.

To learn more, review the Medication Guide **HERE**.

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.

FABHALTA® (iptacopan) 200 mg capsules

CLINICAL BREAKTHROUGH HEMOLYSIS AND MAJOR ADVERSE VASCULAR EVENTS OBSERVED WITH FABHALTA

C5 Inhibitor-Experienced Adults With PNH | **24-Week Switch Clinical Trial**

- The data are for observation only. It cannot be determined by this study whether the following results were due to treatment with FABHALTA or if they happened by chance. No conclusions or comparisons between FABHALTA and C5 inhibitors can be made

Percentage of people who experienced clinical breakthrough hemolysis:

- Two out of 62 people (3%) who switched to FABHALTA and 6 out of 35 people (17%) who stayed on C5 inhibitors (SOLIRIS® [eculizumab] or ULTOMIRIS® [ravulizumab-cwvz]) experienced clinical breakthrough hemolysis

The number of people who experienced major adverse vascular events:

- One person out of 62 experienced a transient ischemic attack, or mini-stroke, while taking FABHALTA, which was determined by the study investigator to be unrelated to treatment vs 0 people of 35 on SOLIRIS or ULTOMIRIS during the 24-week clinical trial

Complement Inhibitor-Naive Adults With PNH | **24-Week Clinical Trial**

- The data from this additional analysis are exploratory and presented for observation only. It is unknown if the following results were due to FABHALTA or not. We cannot make conclusions from exploratory data, but it is useful to help guide future research

No one in the trial experienced clinical breakthrough hemolysis or a major adverse vascular event.

- Clinical breakthrough hemolysis was defined in the study as a person who experienced a decrease of ≥2 g/dL in hemoglobin compared to the last assessment or within 15 days, or other significant increase in PNH-related signs or symptoms. People were also screened for other lab criteria
- Major adverse vascular events were defined in the study as events involving the blood vessels such as stroke, heart attack, and blood clots

Important Safety Information (continued)

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

The most common side effects of FABHALTA in adults include:

- Headache
- Nasal congestion, runny nose, cough, sneezing, and sore throat (nasopharyngitis)
- Diarrhea
- 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.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

SUMMARY OF IMPORTANT INFORMATION FOR 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.

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 fatal 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 therapy 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.
    Call your health care provider or get emergency medical care right away if you have 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 a 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 information about the symptoms of serious infections.
- Make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that 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 Full Prescribing Information, including Boxed WARNING and Medication Guide.

Please see additional Important Safety Information throughout and Summary of Important Information on pages 17–18.

SUMMARY OF IMPORTANT INFORMATION FOR FABHALTA (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 are starting 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.

If you have PNH and you stop taking FABHALTA, your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA. **Stopping treatment with 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 (ED)

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
- 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.

Please see Full Prescribing Information, including Boxed WARNING and Medication Guide.

Please see additional Important Safety Information throughout and Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

REPLACE PNH INFUSIONS WITH AN INNOVATIVE ORAL TREATMENT

Take FABHALTA at home, or on the go

- One capsule, twice a day, every day
- With or without food
- Swallow the capsules whole. Do not open, break or chew capsules
- You do not need to refrigerate FABHALTA
  - 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)

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

What you need to know about switching to FABHALTA:

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

If you have PNH and you stop taking FABHALTA:

- Your health care provider will need to monitor you closely for at least 2 weeks after stopping FABHALTA
- Stopping treatment with FABHALTA may cause a breakdown of red blood cells due to PNH
- Symptoms or problems that can happen due to RBC breakdown 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 that you take FABHALTA exactly as your health care provider tells you to lower the possibility of breakdown of red blood cells due to PNH**

Take FABHALTA exactly as your doctor tells you.

Don't change the dose or stop taking FABHALTA unless your doctor tells you.

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 fatal if not recognized and treated early.

Please see additional Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

NOVARTIS PATIENT SUPPORT CAN HELP SUPPORT YOU EVERY STEP OF THE WAY

Novartis Patient Support™

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

Once you and your health care provider decide to begin FABHALTA® (iptacopan), you can sign up or designate a loved one to sign you up for Novartis Patient Support. It's a personalized program that can help you start, stay, and save on treatment.

Now, you have a dedicated team in your corner to help with:

Navigating the Insurance Process

Your dedicated Novartis Patient Support team will work with your provider to help navigate insurance coverage for your medication.

Financial Support

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

Vaccination Support

Our dedicated Novartis Patient Support team can help you locate vaccinations.

Ongoing Support

Your dedicated Novartis Patient Support team is here for you with personalized support throughout your treatment and not just at the beginning.

Sign up for Novartis Patient Support

There are a few different ways to start getting support:

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

$0 CO-PAY PLUS OFFER*

If you have private insurance, your co-pay could be as little as $0 with your Co-Pay Plus offer for FABHALTA.

If you have private insurance and your prescription coverage isn't initially approved, you may be able to get up to 12 months of FABHALTA® (iptacopan) for free through the FABHALTA Bridge Program.† Your medication's cost will be covered for up to 12 months while coverage is pursued. Ask your health care provider to help you sign up for FABHALTA Bridge Program.

See terms and conditions indicated with footnote symbols on the next page.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 17–18.

FABHALTA® (iptacopan) 200 mg capsules

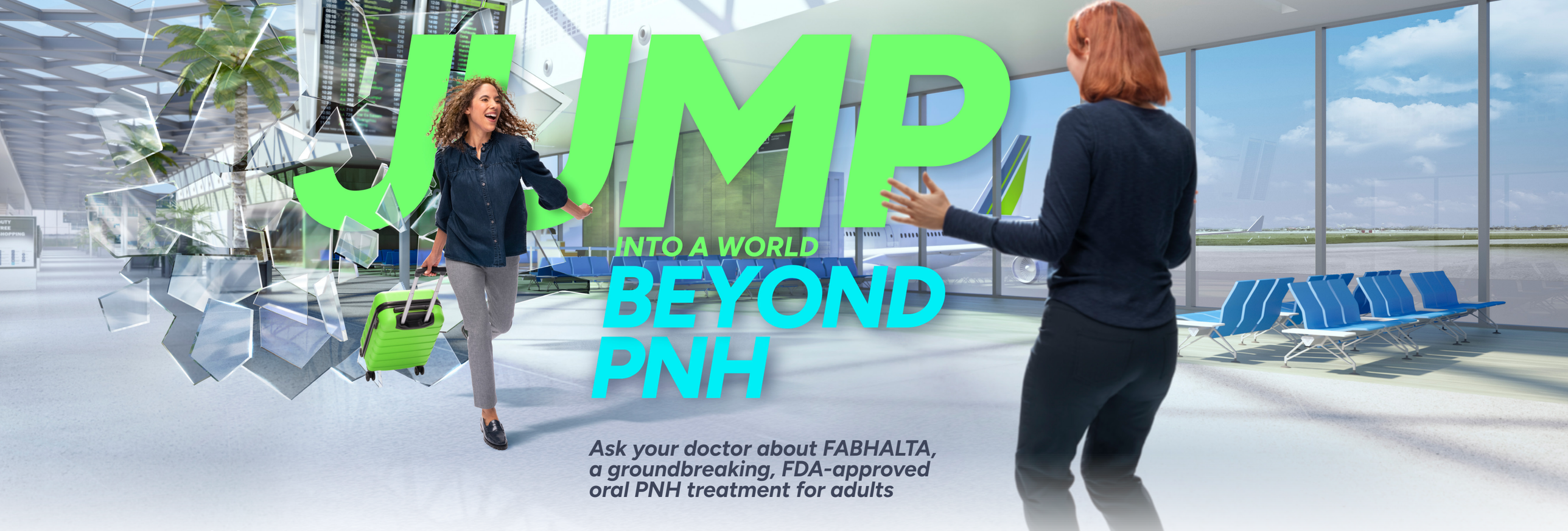
NOVARTIS PATIENT SUPPORT TERMS AND CONDITIONS

Co-Pay Plus

*Limitations apply. Patients with commercial insurance coverage for FABHALTA may receive up to $20,000 in annual co-pay benefits for the cost of FABHALTA and up to $1,000 for qualifying vaccination costs (excluding administrative fees). Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the program. Valid only in the United States, Puerto Rico and select territories. Void where prohibited by law. Additional restrictions may apply. This program is not health insurance. program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the program and discontinue support at any time without notice.

Bridge Information

†Limitations apply. Patients with commercial insurance, a valid prescription for FABHALTA, and a denial of insurance coverage based on a prior authorization requirement may receive a monthly dose for up to 12 months or until insurance coverage approval, whichever occurs first. Not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state program, or where prohibited by law. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional restrictions may apply. Novartis reserves the right to rescind, revoke or amend this Program without notice.



Ask your doctor about FABHALTA, a groundbreaking, FDA-approved oral PNH treatment for adults

Patient portrayal.

Improved hemoglobin (Hb) levels with the first FDA-approved oral treatment for adults with PNH. In a study of 62 people receiving FABHALTA and 35 people receiving C5 inhibitors, 82% of people taking FABHALTA had an increase in Hb ≥2 g/dL vs 0% of people taking C5 inhibitors. 68% of people taking FABHALTA had Hb levels ≥12 g/dL vs 0% of people taking C5 inhibitors. These results were achieved in the absence of red blood cell transfusions after 24 weeks.

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.

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 fatal if not recognized and treated early.

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NOVARTIS

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