LESS IS MORE.

Less PNH symptoms.[a]

More disease control.[b]

ULTOMIRIS is the #1 prescribed PNH treatment in adults[c] that works to reduce the risk of intravascular hemolysis, blood clots, fatigue, and the need for transfusions. ULTOMIRIS is the only long-acting PNH medication that can provide up to 8 weeks of freedom between treatments.*

*Starting 2 weeks after the initial loading dose, maintenance doses are administered every 8 weeks for adults and every 4 or 8 weeks for pediatric patients (depending on body weight).

[a]In a clinical trial, adults receiving ULTOMIRIS had fewer PNH symptoms—fatigue, abdominal pain, shortness of breath, difficulty swallowing, chest pain, hemoglobinuria, and erectile dysfunction—than they did before they started treatment.

[b]In a clinical trial, the levels of LDH—an established measure of intravascular hemolysis and PNH disease activity—in the blood of adults with PNH had dropped within normal range by 4 weeks of starting ULTOMIRIS treatment and stayed there throughout one year.

[c]Based on US market share data.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

INDICATION

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ULTOMIRIS?
ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**

1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection**: fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ALEXION®
AstraZeneca Rare Disease

What does PNH mean?

P

Paroxysmal

A sudden attack

Even though hemolysis due to PNH is always occurring, symptoms can worsen from time to time. This worsening happens when the immune system is more active, like during an infection or illness.

N

Nocturnal

At nighttime

The part of the immune system that causes hemolysis is more active at night, so symptoms like hemoglobinuria are often most obvious in the morning. However, hemolysis is happening at some level in people with PNH all the time, night and day.

H

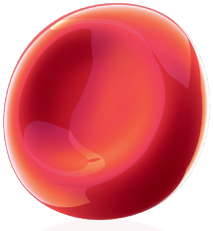
Hemoglobinuria

Hemoglobin in the urine

Red blood cells (RBCs) destroyed by hemolysis release a dark red protein called hemoglobin. The body gets rid of the hemoglobin in the urine, which turns reddish or very dark. Not everyone with PNH has hemoglobinuria.

RBC=red blood cell.

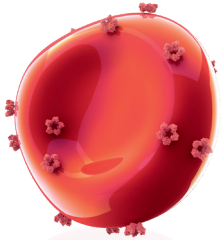
How C5 and intravascular hemolysis cause PNH symptoms



1 PNH red blood cells (RBCs) are vulnerable to attack by complement protein C5

In PNH, a change in the bone marrow causes some RBCs to be made without important protective proteins on their surface.

Without these proteins, the PNH RBCs are vulnerable to a part of your body's immune system called complement, including a protein within the complement system called C5.



2 C5 plays a key role in intravascular hemolysis (IVH)

C5 usually works to destroy disease-causing pathogens like bacteria by poking holes in them.

In PNH, C5 also targets RBCs that are missing protective proteins.

Uncontrolled C5 destroys PNH red blood cells inside blood vessels in a process called IVH.

3 IVH causes PNH symptoms and other effects

IVH is the main cause of PNH symptoms and can lead to blood clots and other PNH-related effects in the body, such as organ damage.

If you have PNH, you are at constant risk of C5-driven IVH.

IVH=intravascular hemolysis; RBC=red blood cell.

ULTOMIRIS is designed to control intravascular hemolysis and PNH symptoms—with fewer infusions

Removes C5

ULTOMIRIS binds to the complement protein C5 to block its activation and remove it from the bloodstream.

Reduces hemolysis

By binding and eliminating C5, ULTOMIRIS controls intravascular hemolysis (IVH) of PNH red blood cells.

Long-acting control

ULTOMIRIS stays in the body for a long period of time, allowing up to 8 weeks between infusions.[a] **With the possibility of every-8-week dosing, ULTOMIRIS means your plans don't have to center around frequent infusions.**

[a]Starting 2 weeks after the initial loading dose, maintenance doses are administered every 8 weeks for adults and every 4 or 8 weeks for pediatric patients (depending on body weight).
IVH=intravascular hemolysis.

ULTOMIRIS is the first and only FDA-approved, long-acting medication for adults and children 1 month of age and older with PNH.
Long-acting control of IVH means more time between infusions.

SELECT IMPORTANT SAFETY INFORMATION

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start ULTOMIRIS right away and are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

ULTOMIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae, Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with ULTOMIRIS. Certain people may be at risk of serious infections with gonorrhea.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ULTOMIRIS was studied in the largest-ever PNH clinical trial program

The ULTOMIRIS clinical studies each lasted 6 months and included...

246 adults
who had no prior PNH treatment with a complement inhibitor called SOLIRIS® (eculizumab)

13 children
8 who had received prior PNH treatment with SOLIRIS and 5 who had not

FACIT=Functional Assessment of Chronic Illness Therapy; LDH=lactate dehydrogenase.

The effects of ULTOMIRIS on PNH were measured in several different ways, including...

Amount of free C5 in the blood

Low levels mean that C5 is being blocked by ULTOMIRIS

Amount of LDH in the blood

Low or normalized LDH levels are associated with control over intravascular hemolysis

Rate of transfusion avoidance

The number of people who did not need transfusions during the study can reflect how well hemolysis is being controlled

Rate of breakthrough hemolysis

Breakthrough hemolysis is red blood cell destruction that happens despite ongoing treatment

Breakthrough hemolysis events were defined as experiencing at least 1 new or worsening sign or symptom of hemolysis that occurs along with elevated LDH levels (after LDH levels were previously reduced through treatment)

Rate of adverse events involving blood vessels

The number of adults who had adverse events involving blood vessels—which included blood clots—in the study can indicate how well PNH-induced clotting is being controlled

Hemoglobin stabilization

Stable levels of hemoglobin in the blood can mean that anemia is under control

Fatigue

Fatigue was measured using a scale called FACIT-Fatigue. Scores on the scale range from 0 to 52, with higher scores indicating less fatigue

The reported fatigue in these studies may be an underestimation or overestimation

SELECT IMPORTANT SAFETY INFORMATION

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS.

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

ULTOMIRIS reduced the risk of PNH signs and symptoms

In adults who received ULTOMIRIS and had no prior PNH treatment:

74%

(92 out of 125 adults)

did not need blood transfusions

54%

(67 out of 125 adults)

had normalized LDH levels

On average, there was a 76.8% reduction in LDH levels from the starting point of the study

100%

(125 out of 125 adults)

had levels of free C5 that indicated immediate, complete, and sustained C5 inhibition

This measure shows how well ULTOMIRIS is working to block C5 activity

96%

(120 out of 125 adults)

were free of breakthrough hemolysis events

The 5 breakthrough events that happened in the study were associated with an infection or an unknown cause, not elevated free C5 levels

98.4%

(123 out of 125 adults)

were free of blood clots

68%

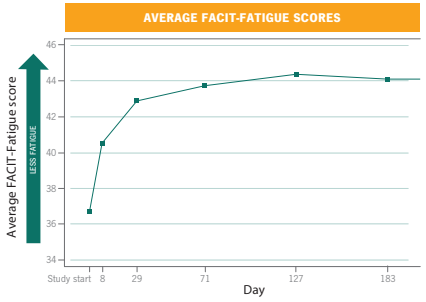
(85 out of 125 adults)

had stable hemoglobin levels

Decreased fatigue

The average FACIT-Fatigue score **improved by an average of 7.1 points** over the course of the study

The average score for the adult general population has been estimated to be **43.5**



There was no observable difference in fatigue between ULTOMIRIS and SOLIRIS® (eculizumab) after 26 weeks of treatment compared to baseline as measured by the FACIT-Fatigue instrument. Patient-reported fatigue may be an underestimation or overestimation, because patients were not blinded to treatment assignment.

The most frequent adverse reactions (≥10%) with ULTOMIRIS were upper respiratory tract infection and headache.

FACIT=Functional Assessment of Chronic Illness Therapy; LDH=lactate dehydrogenase.

These effects in adults stayed consistent through 1 year of treatment with ULTOMIRIS. A corresponding trial of SOLIRIS-experienced patients showed similar results.

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ULTOMIRIS is the first and only FDA-approved medication for both children* and adults with PNH

*One month of age and older.

In children who received ULTOMIRIS:

100%

(13 out of 13 children)

had levels of free C5 that indicated immediate, complete, and sustained C5 inhibition

This measure shows how well ULTOMIRIS is working to block C5 activity

85%

(11 out of 13 children)

did not need blood transfusions

69%

(9 out of 13 children)

had stable hemoglobin levels

100%

(13 out of 13 children)

were free of breakthrough hemolysis events

48%

Average reduction in LDH levels

in the 5 children who had not received prior PNH treatment with SOLIRIS

4.7%

Average increase in LDH levels

in the 8 children who had received prior PNH treatment with SOLIRIS

Decreased fatigue

All 5 children who had not received prior PNH treatment with SOLIRIS had a clinically relevant decrease in fatigue over the 26-week study, as measured by Pediatric FACIT-Fatigue

The 8 children who had received prior PNH treatment with SOLIRIS also had a slight decrease in fatigue

The most common side effects (>20%) of ULTOMIRIS in children with PNH were upper respiratory tract infection, anemia, abdominal pain, and headache.

FACIT=Functional Assessment of Chronic Illness Therapy; LDH=lactate dehydrogenase.

SELECT IMPORTANT SAFETY INFORMATION

If you have PNH and you stop receiving ULTOMIRIS, your healthcare provider will need to monitor you closely for at least 16 weeks after you stop ULTOMIRIS. Stopping ULTOMIRIS may cause breakdown of your red blood cells due to PNH. Symptoms or problems that can happen due to red blood cell breakdown include: drop in your red blood cell count, tiredness, blood in your urine, stomach-area (abdomen) pain, shortness of breath, blood clots, trouble swallowing, and erectile dysfunction (ED) in males.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

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Less infusions mean more freedom

ULTOMIRIS, administered up to every 8 weeks,[a] gives people with PNH the possibility of more freedom and flexibility between treatments.

[a]Starting 2 weeks after the initial loading dose, maintenance doses are administered every 8 weeks for adults and every 4 or 8 weeks for pediatric patients (depending on body weight).

ULTOMIRIS is given through a vein by intravenous (IV) infusion.

If you are an adult with PNH

You will usually receive an infusion of ULTOMIRIS every 8 weeks that begins 2 weeks after your starting dose

If you are a child with PNH

You will usually receive an infusion of ULTOMIRIS every 4 or 8 weeks, depending on your body weight, that begins 2 weeks after your starting dose

Infusion tips

You might be feeling unsure about getting intravenous infusions, but there are ways to improve the experience:

- Drink plenty of water. This will help your doctor find your veins more easily
- Wear comfortable, layered clothing that you can adjust in case you become overly warm or cool
- Keep busy during your infusion by reading, watching TV, or doing any other activity you can do while seated and remaining still

You may need to arrive early or stay late after your treatment, depending on the requirements of your treatment center.

After each infusion, you should be monitored for at least 1 hour for infusion-related reactions.

Infusion-related reactions

Infusion-related reactions may happen during your ULTOMIRIS infusion. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, feeling faint or discomfort in your arms or legs. Tell your doctor or nurse right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion reaction, including:

- Chest pain
- Trouble breathing or shortness of breath
- Swelling of your face, tongue, or throat
- Feel faint or pass out

Your doctor will treat your symptoms as needed.

SELECT IMPORTANT SAFETY INFORMATION

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion-related reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Sticking to your prescribed treatment schedule

If you miss an ULTOMIRIS infusion, call your doctor right away.

To get the most from your ULTOMIRIS therapy, stick with your treatment schedule.

For ULTOMIRIS to effectively reduce hemolysis, the drug needs to stay above a certain level in your blood. However, like all drugs, ULTOMIRIS is broken down and removed from your body over time.

The time that it takes your body to remove half of the drug is called the "half-life" of that drug. **A regular therapy schedule keeps ULTOMIRIS in your body at a level where it works best.**

ULTOMIRIS should be infused according to the recommended dosing schedule for you to get the most out of your treatment. If the level of ULTOMIRIS in your body gets too low, hemolysis can occur.

Hemolysis is the underlying cause of major health problems in PNH. Missing doses can allow hemolysis to happen. **Work closely with your healthcare team to keep track of your infusions, and check in with your doctor regularly to best manage your PNH.**

SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of ULTOMIRIS in people treated for PNH are upper respiratory tract infection and headache.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

What do I need to know before taking ULTOMIRIS?

Before you receive ULTOMIRIS, tell your doctor about all of your medical conditions, including if you:

- Have an infection or fever
- Are pregnant or plan to become pregnant. It is not known if ULTOMIRIS will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS

Transfusion requirements

Transfusions may still be necessary in patients taking ULTOMIRIS. In PNH, your bone marrow continues to make cells that are missing protective proteins, putting PNH red blood cells at constant risk of hemolysis.

In some patients, the bone marrow may also have trouble simply making red blood cells, meaning fewer cells get produced. This is one reason some patients on ULTOMIRIS might still need blood transfusions.

Lab tests that your doctor may order

High-sensitivity flow cytometry *to measure* **clone size**

- Clone size is the percentage of blood cells in your body that have been affected by PNH and, therefore, do not have the protective proteins that blood cells usually have on their surface
- This test measures the actual number of red and white blood cells affected by PNH in a small sample of blood taken from your arm
- It is the standard test for confirming whether or not you have PNH, and, through continued monitoring, your doctor can tell if your clone size is changing over time

LDL level *to measure* **hemolysis**

- Lactate dehydrogenase (LDH) is an enzyme found in red blood cells that is released during hemolysis
- Knowing how much LDH is in your blood helps show how much hemolysis is happening in your body
- Your LDH level, in comparison with your LDH level before starting ULTOMIRIS, may show how well you are responding to ULTOMIRIS

Hemoglobin *to test for* **anemia**

- Hemoglobin is usually located inside red blood cells, but it is released into the bloodstream when the cells are destroyed by hemolysis. This form of hemoglobin, called serum free hemoglobin, is harmful and is the cause of many signs, symptoms, and serious health problems associated with PNH
- The hemoglobin test that your doctor might run to see if you have anemia measures the hemoglobin that is still located inside intact red blood cells, not serum free hemoglobin
- Low hemoglobin levels in people with PNH may be due to PNH-related hemolysis, or they may be due to problems with red blood cell production caused by underlying bone marrow problems like aplastic anemia or myelodysplastic syndrome (MDS)

Platelet counts *to measure* **platelet levels**

- The platelet count measures the amount of platelets in your blood. Platelets are involved in blood clot formation and play an important role in helping you heal from injury
- PNH may affect your platelet level
- Your platelet count might stay the same even after months of treatment, regardless of a decrease in the LDH level and a need for blood transfusions

Creatinine *to assess* **signs of kidney damage**

- Levels of creatinine, a waste product in the blood, can show how well your kidneys are working
- The creatinine level can help indicate if and how PNH is affecting your kidneys

You must receive a meningococcal vaccine at least 2 weeks before your first dose of ULTOMIRIS if you have not already had this vaccine

Get vaccinated.

ULTOMIRIS can lower the ability of your immune system to fight some infections. Before taking ULTOMIRIS, you must be vaccinated against meningococcal infection, a severe infection that can occur in the blood and that requires immediate medical attention. Your doctor or nurse will make sure you receive this vaccine at least 2 weeks before your first infusion.

If your doctor decided that urgent treatment with ULTOMIRIS is needed, you should get the meningococcal vaccine as soon as possible.

If you had a meningococcal vaccine in the past, you might need additional vaccination before starting ULTOMIRIS. Your doctor will decide if you need additional meningococcal vaccination.

What are the symptoms of meningococcal infection?

The same mechanism that ULTOMIRIS uses to control hemolysis can increase your risk of getting an infection, especially a meningococcal infection. Call your doctor or get emergency medical care right away if you get any of these signs or symptoms of a meningococcal infection:

- Headache with nausea or vomiting
- Headache and fever
- Headache with a stiff neck or stiff back
- Fever
- Fever and a rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light

Carry your Patient Safety Information Card now.

The Patient Safety Information Card lists the signs and symptoms of a meningococcal infection and tells you what to do if you experience any of them.

Start carrying the card today, and carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ULTOMIRIS.

It is important to show this card to any doctor or nurse who treats you. This will help them diagnose and treat you quickly.

PATIENT SAFETY CARD

Important Safety Information for Patients Taking ULTOMIRIS® (ravulizumab-cwvz)

ULTOMIRIS can lower the ability of your immune system to fight infections, **especially meningococcal infection, which requires immediate medical attention.** If you experience any of the following symptoms, you should immediately call your doctor or seek emergency medical care, preferably in a major emergency medical care center:

- headache with nausea or vomiting
- headache and a fever
- headache with a stiff neck or stiff back
- fever
- fever and a rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Get emergency medical care right away if you have any of these signs or symptoms and show this card.

Keep this card with you at all times, even if you stop using ULTOMIRIS. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ONESOURCE®
Personalized Patient Support from Alexion

OneSource™ is here to help

$0 out-of-pocket costs for eligible patients[a,b]

- The Alexion OneSource CoPay Program provides financial assistance by covering eligible patients' out-of-pocket medication and infusion costs associated with ULTOMIRIS
- Valid only for patients with commercial insurance who have a valid prescription for a US FDA–approved indication of ULTOMIRIS. Not valid for costs eligible to be reimbursed by government insurance programs[c] or other federal or state programs (including any state prescription drug assistance programs)
- Additional requirements may apply. Contact Alexion OneSource for more information on patient eligibility

You're not alone. Alexion OneSource is available at no cost to people living with PNH, providing one-on-one support. We are ready to help you with:

Education

- Resources and materials about PNH
- Answers to questions about PNH and treatment logistics

Health insurance navigation

- Helping you understand ULTOMIRIS health insurance coverage
- Exploring alternative funding options and financial resources

Continuity of care

- Personalized support in maintaining therapy during major life events, such as a move or a change in job, insurance status, or doctor

Community connections

- Information about in-person and online meetings and events
- Connecting you with other people living with PNH

Contact OneSource at 1-888-765-4747, email OneSource@Alexion.com, or visit AlexionOneSource.com

*Based on typical commercial patient out-of-pocket deductible limits.
†Additional terms and conditions apply. Please contact OneSource with additional questions.
‡Includes Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense, or TRICARE. Patients residing in Massachusetts, Michigan, Minnesota, and Rhode Island are eligible for assistance with medication costs but are not eligible for assistance with infusion costs.

Resources for people living with PNH

It is natural to think you are alone when you are diagnosed with PNH, because it is a rare disease. Communicating with others who have had similar experiences and who understand can make a difference.

The Aplastic Anemia and MDS International Foundation (AAMDSIF)

Supports, connects, and educates patients, caregivers, and health professionals on bone marrow failure diseases worldwide. It promotes and invests in collaborative clinical research to accelerate the discovery of better treatments and cures for aplastic anemia, myelodysplastic syndrome (MDS), PNH, and related bone marrow failure diseases.

National Organization for Rare Disorders (NORD)

A not-for-profit organization dedicated to helping people with rare disorders such as PNH.

These organizations are independent nonprofit organizations. Alexion is not responsible for information they may provide.

To learn more, visit ULTOMIRIS.com

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial

INDICATION & IMPORTANT SAFETY INFORMATION

INDICATION

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

IMPORTANT SAFETY INFORMATION

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

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

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**

1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:** fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start ULTOMIRIS right away and are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

ULTOMIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with ULTOMIRIS. Certain people may be at risk of serious infections with gonorrhea.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS.

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

If you have PNH and you stop receiving ULTOMIRIS, your healthcare provider will need to monitor you closely for at least 16 weeks after you stop ULTOMIRIS. Stopping ULTOMIRIS may cause breakdown of your red blood cells due to PNH. Symptoms or problems that can happen due to red blood cell breakdown include: drop in your red blood cell count, tiredness, blood in your urine, stomach-area (abdomen) pain, shortness of breath, blood clots, trouble swallowing, and erectile dysfunction (ED) in males.

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion-related reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

The most common side effects of ULTOMIRIS in people treated for PNH are upper respiratory tract infection and headache.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Glossary

anemia
The condition of having a lower-than-normal number of red blood cells or amount of hemoglobin. Anemia reduces the ability of the blood to carry oxygen and is sometimes found in PNH.

blood clots
Blood clots form when parts of your body's blood clump together. In a healthy body, this clumping can stop bleeding when you're cut or injured, but in certain conditions, these clumps can block blood flow in the veins and arteries, which can be dangerous. In PNH, a clot can happen at any time and can cause serious health problems.

bone marrow
Soft tissue inside your large bones. Stem cells, contained in your bone marrow, work to create parts of your blood: red blood cells, white blood cells, and platelets.

breakthrough hemolysis
Breakthrough hemolysis is defined as at least 1 new or worsening symptom or sign of hemolysis that occurs along with elevated LDH levels (after LDH levels were previously reduced through treatment). Breakthrough hemolysis may lead to complications.

C5
Part of the complement system. C5 usually works to destroy disease-causing pathogens like bacteria by poking holes in them. In PNH, C5 also targets red blood cells that are missing protective proteins.

complement
Part of the immune system. In healthy individuals, complement is a sequence of reactions in the blood that is part of the body's natural defense system. It helps fight against bacteria and other foreign matter in the body.

FACIT-Fatigue
FACIT stands for Functional Assessment of Chronic Illness Therapy. The FACIT-Fatigue scale can be used to measure fatigue. FACIT-Fatigue scores can range from 0 to 52, with higher scores indicating less fatigue.

hemolysis
Breakdown of red blood cells. Hemolysis is the main cause of major health problems in PNH.

intravascular hemolysis (IVH)
Hemolysis that occurs inside the blood vessels. In PNH, IVH is caused by complement, including the protein C5, and is the major cause of PNH signs and symptoms.

kidney damage
Healthy kidneys clean your blood by removing excess fluid, minerals, and wastes. They also make hormones that keep your bones strong and your blood healthy. In PNH, the blood cells that burst release iron and hemoglobin into your system. As a result, blood vessels and tissues in the kidneys can get injured. This injury reduces the level at which your kidneys work.

lactate dehydrogenase (LDH)
LDH is an enzyme found in red blood cells that is released during hemolysis. Lab tests to measure LDH levels can help to assess PNH disease activity.

paroxysmal nocturnal hemoglobinuria (PNH)
A disease where red blood cells are created without certain protective proteins. This causes them to break down (a process called hemolysis) and can result in serious health problems. Signs and symptoms include stomach pain, difficulty swallowing, anemia, shortness of breath, and fatigue. Life-threatening complications from PNH include blood clots, which may lead to kidney failure and damage to your other organs.

proteins
Proteins are the building blocks of life. The body needs proteins to repair and maintain itself. In PNH, some or all red blood cells lack an important protective protein. Without this protein, PNH red blood cells are attacked by complement, part of the body's natural defense system, resulting in hemolysis.

red blood cells (RBCs)
A type of cell found in your blood that delivers oxygen and removes waste (carbon dioxide) in your body. Red blood cells affected by PNH are attacked and destroyed because they are missing a protective protein.

white blood cells (WBCs)
A type of cell found in your blood that helps your immune system fight disease and infection.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

The #1 treatment[a] for adults with PNH is also FDA approved for children

$0 out-of-pocket costs for eligible patients[b,c]

- The Alexion OneSource CoPay Program provides financial assistance by covering eligible patients' out-of-pocket medication and infusion costs associated with ULTOMIRIS
- Valid only for patients with commercial insurance who have a valid prescription for a US FDA–approved indication of ULTOMIRIS. Not valid for costs eligible to be reimbursed by government insurance programs[d] or other federal or state programs (including any state prescription drug assistance programs)
- Additional requirements may apply. Contact Alexion OneSource for more information on patient eligibility
- The most common side effects of ULTOMIRIS in people treated for PNH are upper respiratory tract infection and headache

[a]Based on US market share.
[b]Based on typical commercial patient out-of-pocket deductible limits.
[c]Additional terms and conditions apply. Please contact OneSource with additional questions.
[d]Includes Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense, or TRICARE. Patients residing in Massachusetts, Michigan, Minnesota, and Rhode Island are eligible for assistance with medication costs but are not eligible for assistance with infusion costs.

Talk to your doctor about ULTOMIRIS and visit ULTOMIRIS.com

ONESOURCE® Personalized Patient Support from Alexion

Call 1-888-765-4747, email OneSource@Alexion.com, or visit AlexionOneSource.com

INDICATION

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

SELECT IMPORTANT SAFETY INFORMATION

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

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

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**

1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:** fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ALEXION®
AstraZeneca Rare Disease