

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 Important Safety Information throughout and full accompanying Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

ALEXION®
AstraZeneca Rare Disease

What is PNH?

P

Paroxysmal

A sudden attack

Even though hemolysis due to PNH is always occurring, symptoms can worsen when the immune system is more active (like during an infection or illness).

N

Nocturnal

At nighttime

It was once thought that hemolysis in PNH was worse at night, so symptoms like dark urine often show up in the morning. We know now that red blood cells are broken down at some level in people with PNH all the time, day and night.

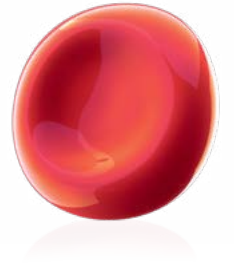
H

Hemoglobinuria

Hemoglobin in the urine

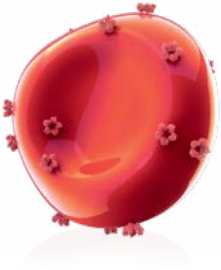
When red blood cells (RBCs) break down, they release a dark red protein called hemoglobin, which may make urine appear red or very dark. Not everyone with PNH has this symptom.

What causes PNH symptoms?



1 Unprotected red blood cells (RBCs) in PNH

In PNH, a change in the bone marrow causes some red blood cells to be made without “protective proteins,” which exposes them to a part of your body’s immune system called complement.



2 C5 triggers intravascular hemolysis (IVH)

When C5, a protein within the complement system, works properly, it destroys harmful germs. For those with PNH, C5 targets the unprotected RBCs, destroying them inside blood vessels. This process is called IVH.



3 IVH causes PNH symptoms

IVH is the main cause of life-threatening PNH symptoms and can lead to blood clots and other serious symptoms such as organ damage. The risk of IVH is lifelong. When C5 isn’t under control, PNH can get worse and the risk of experiencing symptoms increases.

C5=a protein within the complement system; PNH=paroxysmal nocturnal hemoglobinuria.

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



Removes C5



Reduces hemolysis



Provides long-acting control up to 8 weeks between infusions[a]

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.

[a]Two weeks after the intravenous loading dose, ULTOMIRIS is infused intravenously every 8 weeks for most people and every 4 weeks for children weighing less than 44 pounds (20 kilograms).
C5=a protein within the complement system; FDA=Food and Drug Administration; IVH=intravascular hemolysis; PNH=paroxysmal nocturnal hemoglobinuria.

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.

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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

PNH=paroxysmal nocturnal hemoglobinuria.



Actor portrayal.

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. It is not known if ULTOMIRIS will harm your unborn baby.
  - Pregnancy Registry: There is a registry for pregnant women who take ULTOMIRIS to check the health of the pregnant mother and her baby. If you are pregnant or become

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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 require blood transfusions, which reflects how well hemolysis is being controlled

54%
(67 out of 125 adults)
had normalized LDH levels
On average, there was a 76.8% reduction in LDH levels from the study start

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

100%
(125 out of 125 adults)
had lower levels of free C5 that indicated immediate, complete, and long-term C5 inhibition

This measure shows how well ULTOMIRIS is blocking 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

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

98.4%
(123 out of 125 adults)
were free of blood clots, which indicates how well PNH-induced clotting is being controlled

68%
(85 out of 125 adults)
had stable hemoglobin levels, which can mean that anemia is under control

Decreased fatigue

The average FACIT-Fatigue score ***improved by an average of 7.1 points*** *during the study.*
Scores on the scale range from 0 to 52, with higher scores indicating less fatigue

The most common side effects (≥10%) of ULTOMIRIS in adults with PNH were upper respiratory tract infection and headache.

These primary and secondary outcomes in adults stay consistent through 1 year of treatment with ULTOMIRIS. A corresponding trial of SOLIRIS-experienced showed similar results.

There was no observable difference in fatigue between ULTOMIRIS and SOLIRIS 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.

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).

C5=a protein within the complement system; FACIT=Functional Assessment of Chronic Illness Therapy; LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria.

SELECT IMPORTANT SAFETY INFORMATION

pregnant while taking ULTOMIRIS, talk to your healthcare provider about how you can join this registry or you may contact the registry at 1-833-793-0563 or www.UltomirisPregnancyStudy.com to enroll.

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ULTOMIRIS is the first and only FDA-approved medication for children[a] with PNH

In children who received ULTOMIRIS:

100%
(13 out of 13 children)
had levels of free C5 indicating immediate, complete, and long term C5 inhibition

This measure shows how well ULTOMIRIS is blocking C5 activity

85%
(11 out of 13 children)
did not need blood transfusions, which reflects how well hemolysis is being controlled

69%
(9 out of 13 children)
had stable hemoglobin levels, which can mean that anemia is under control

100%
(13 out of 13 children)
were free of breakthrough hemolysis events

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

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.

[a]One month of age and older

C5=a protein within the complement system; FACIT=Functional Assessment of Chronic Illness Therapy; FDA=Food and Drug Administration; LDH=lactate dehydrogenase; PNH=paroxysmal nocturnal hemoglobinuria.

SELECT IMPORTANT SAFETY INFORMATION

- 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.

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.

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

Fewer infusions mean more cherished moments



ULTOMIRIS, with doses as few as 6 to 7 times per year,[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.

PNH=paroxysmal nocturnal hemoglobinuria.

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.

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, stomach (abdominal) pain, muscle spasms,

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ULTOMIRIS intravenous (IV) infusions

Where will I get my infusion?

You'll receive ULTOMIRIS through an intravenous (IV) infusion at an infusion clinic or healthcare provider's office. OneSource™ can help you locate the clinic nearest you. Call **1-888-765-4747** for more information. You may also be eligible to receive your infusions at home, administered by a nurse.

Can I have my infusion at home?

You may be able to receive ULTOMIRIS infusions from the comfort of your own home, administered by a nurse. To find out more, connect with **OneSource support**.

What should I do before my infusion?

Dress in comfortable clothes. Hydrate yourself as much as possible prior to your infusion. This can make it easier for the nurses and staff to find a vein for your IV.

How long will it take?

For most adults, infusions last less than an hour. After each infusion, the nurse or staff will ask you to stay for at least 1 hour to monitor you for any infusion-related reactions.

I'm switching to ULTOMIRIS. Anything I need to know?

If you're switching from SOLIRIS, you will get your first ULTOMIRIS infusion at the time of your next scheduled SOLIRIS dose.

If you're switching from another treatment, talk to your healthcare provider.

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

SELECT IMPORTANT SAFETY INFORMATION

changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, or bad taste. 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.

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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.

Never miss a dose of ULTOMIRIS

Sign up for our free text-based reminder service

Introducing our free text-based reminder service for people who are receiving ULTOMIRIS! To enroll:

- Sign up and select your reminder times, based on your dosing schedule
- Receive alerts when it's time for your next infusion
- It's easy, convenient, and free!

Scan the QR code to sign up for text message reminders



Actor portrayal.

PNH=paroxysmal nocturnal hemoglobinuria.

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 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.

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Financial assistance may be available

ONESOURCE®
Personalized Patient Support from Alexion

$0

Pay as low as $0 in out-of-pocket costs out-of-pocket costs for eligible patients[a]

With the Alexion OneSource™ CoPay Program, eligible people may save on medication and infusion costs if they:

- Are enrolled in OneSource
- Have commercial insurance that covers some portion of the drug and/or infusion cost
- Have a valid ULTOMIRIS prescription for a US Food and Drug Administration–approved indication
- Are a citizen or permanent resident of the United States or its territories
- Do not have Medicare, Medicaid, or other government insurance[a]



Education

- Educational materials about PNH
- Details about ULTOMIRIS
- Information about the treatment process



Health insurance navigation

- Providing information that explains your insurance coverage for ULTOMIRIS
- Addressing financial concerns or gaps in coverage
- Informing you of infusion centers or other treatment location options nearby



Community connections

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



Ongoing support

- Guiding you through insurance changes or finding new treatment locations
- Navigating your treatment through life events, such as getting married, starting a new job, moving, or traveling
- Working with your healthcare provider and specialty pharmacy to ensure you keep receiving ULTOMIRIS as prescribed

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

[a]The Alexion OneSource CoPay Program is not valid for patients covered by government insurance programs or other federal or state programs (including any state prescription drug assistance programs), including Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense, or TRICARE. People residing in Massachusetts or Rhode Island are eligible for assistance with medication costs but are not eligible for assistance with infusion costs.

PNH=paroxysmal nocturnal hemoglobinuria.

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.

Need Support?

Patient Education Managers (PEMs) are here for you. We offer personalized education and guidance from diagnosis through ongoing care:

- Answering questions
- Explaining PNH and management options
- Connecting you with resources and patient events

We can help in a way that feels right for you.

Find the PEM closest to you:
https://alexiononesource.com/pem-finder

All interactions with PEMs are private and confidential. There is never any obligation to continue services—participation is always voluntary. You are welcome to ask questions or simply learn at your own pace.

For more PNH resources and to hear real-life patient stories, go to ULTOMIRIS.COM/PNH

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Actor portrayal.

ULTOMIRIS is designed for long-lasting PNH control between infusions



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

Scan for full Prescribing Information.

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ALEXION® AstraZeneca Rare Disease