ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/30 mL vial

# ULTOMIRIS® (ravulizumab-cwvz) is the first and only long-acting complement inhibitor.[1]


## How ULTOMIRIS Works

ULTOMIRIS works by inhibiting the C5 protein in the terminal complement cascade, a part of the body's immune system.

ULTOMIRIS is administered intravenously. For patients with PNH, ULTOMIRIS is administered every eight weeks, following a loading dose. For patients with aHUS, ULTOMIRIS is dosed every eight weeks (or every four weeks for pediatric patients less than 20 kg), following a loading dose.

## Clinical Trials

For clinical trial and other information, visit Ultomiris.com

Please see the indications and Important Safety Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis, starting on page 2.

## ULTOMIRIS is approved in the United States for the treatment of two debilitating complement-mediated disorders:

**Paroxysmal Nocturnal Hemoglobinuria (PNH):**

- PNH is a serious ultra-rare blood disorder with devastating consequences. It is characterized by the destruction of red blood cells, which is called hemolysis.[2,3]
- PNH occurs when the complement system—a part of the body's immune system—over-responds, leading the body to attack its own red blood cells.[2,4-7]
- Patients with PNH may experience a range of symptoms, such as fatigue, difficulty swallowing, shortness of breath, abdominal pain, erectile dysfunction, dark-colored urine and anemia.[8-13]
- The most devastating consequence of chronic hemolysis is the formation of blood clots, which can occur in blood vessels throughout the body, damage vital organs, and potentially lead to premature death.[14]
- PNH can strike men and women of all races, backgrounds and ages without warning, with an average age of onset in the early 30s.[15-16]

**Atypical Hemolytic Uremic Syndrome (aHUS):**

- aHUS is an ultra-rare disease that can cause progressive injury to vital organs, primarily the kidneys, via damage to the walls of blood vessels and blood clots.[17]
- aHUS occurs when the complement system—a part of the body's immune system—over-responds, leading the body to attack its own healthy cells.[17-19]
- aHUS can cause sudden organ failure or a slow loss of function over time—potentially resulting in the need for a transplant, and in some cases, death.[19]
- aHUS affects adults and children. Many patients present in critical condition, often requiring supportive care, including dialysis, in an intensive care unit.[17,19]

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## Global Approvals

- Approved in 35+ countries for the treatment of adults with PNH, including in the United States (U.S.), European Union, Canada and Japan
- Approved in the U.S. for the treatment of aHUS to inhibit complement-mediated thrombotic microangiopathy (TMA) for adult and pediatric (one month of age and older) patients

## Patient Access and Support

Alexion's objective is that every patient with PNH or aHUS who can benefit from ULTOMIRIS will have access to it. As part of this commitment, Alexion's OneSource™ program offers a complimentary, personalized support program, designed to support the specific needs of all patients with conditions we serve. Each patient has a dedicated OneSource case manager who can provide them and their families with advanced disease training, health insurance expertise and information about community resources. OneSource case managers can also assist with providing information on alternative funding options and resources.

Patients, caregivers, and healthcare providers in the United States can call 1.888.765.4747 or email OneSource@alexion.com to speak with a case manager.


## U.S. Indications & Important Safety Information for ULTOMIRIS® (ravulizumab-cwvz)

### INDICATIONS:

**What is ULTOMIRIS?**

ULTOMIRIS is a prescription medicine used to treat:

- adults with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- adults and children 1 month of age and older with a disease called atypical Hemolytic Uremic Syndrome (aHUS). ULTOMIRIS is not used in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

It is not known if ULTOMIRIS is safe and effective in children with 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 can lower the ability of your immune system to fight infections.**

- ULTOMIRIS increases your chance of getting serious and life-threatening meningococcal infections that may quickly become life-threatening and cause death if not recognized and treated early.
  1. You must receive meningococcal vaccines at least 2 weeks before your first dose of ULTOMIRIS if you are not vaccinated.
  2. If your doctor decided that urgent treatment with ULTOMIRIS is needed, you should receive meningococcal vaccination as soon as possible.
  3. If you have not been vaccinated and ULTOMIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
  4. If you had a meningococcal vaccine in the past, you might need additional vaccination. Your doctor will decide if you need additional vaccination.
  5. Meningococcal vaccines reduce but do not prevent all meningococcal infections. Call your doctor or get emergency medical care right away if you get any of these signs and 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 and eyes sensitive to light.

**Your doctor will give you a Patient Safety Card about the risk of meningococcal infection**. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. It is important to show this card to any doctor or nurse to help them diagnose and treat you quickly.

Continued on next page

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## References


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**ULTOMIRIS is only available through a program called the ULTOMIRIS REMS**. Before you can receive ULTOMIRIS, your doctor must: enroll in the ULTOMIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a **Patient Safety Card** about the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with a meningococcal vaccine.

**ULTOMIRIS may also increase the risk of other types of serious infections**. Call your doctor right away if you have any new signs or symptoms of infection.

**Who should not receive ULTOMIRIS?**

**Do not** receive ULTOMIRIS if you have a meningococcal infection or have not been vaccinated against meningococcal infection unless your doctor decides that urgent treatment with ULTOMIRIS is needed.

**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, 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 doctor 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 doctor 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.

**If you have aHUS, your doctor will need to monitor you closely for at least 12 months after stopping treatment for signs of worsening aHUS or problems related to a type of abnormal clotting and breakdown of your red blood cells called thrombotic microangiopathy (TMA). Symptoms or problems that can happen with TMA may include**: confusion or loss of consciousness, seizures, chest pain (angina), difficulty breathing and blood clots or stroke.

**What are the possible side effects of ULTOMIRIS?**

**ULTOMIRIS can cause serious side effects including infusion reactions**. Symptoms of an infusion reaction with ULTOMIRIS may include lower back pain, pain with the infusion, 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, and feel faint or pass out.

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

**The most common side effects of ULTOMIRIS in people with aHUS are upper respiratory infection, diarrhea, nausea, vomiting, headache, high blood pressure and fever.**

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 ULTOMIRIS. For more information, ask your doctor or pharmacist. Call your doctor 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 full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.**

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