

Ravulizumab

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for:
 - Paroxysmal nocturnal hemoglobinuria (PNH)
 - Atypical hemolytic uremic syndrome (aHUS)
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Ravulizumab (RAV-yoo-LIZ-yoo-mab): Ultomiris (UL-toh-MEER-is)	Blocks a key protein (C5) in the complement system. This stops the immune system from destroying red blood cells. By preventing that breakdown of red blood cells (called hemolysis), it also helps prevent abnormal clotting and blood vessel damage.	Infusion into a vein (intravenous (IV) infusion).

Treatment Administration and Schedule: Treatment is typically repeated every 4 or 8 weeks, starting 2 weeks after the starting dose. This length of time is called a “cycle”.

Option #1: Every 4 Weeks Cycle

Treatment Name	Cycle 1								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	...	Day 28	Day 1
Ravulizumab	✓								✓

Option #2: Every 8 Weeks Cycle

Treatment Name	Cycle 1								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	...	Day 56	Day 1
Ravulizumab	✓								✓

Appointments: Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help lower the risk of infections	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p>Serious Meningococcal Infections (Boxed Warning)</p>	<p>Description: Ravulizumab increases your chance of getting serious meningococcal infections caused by the <i>Neisseria meningitidis</i> bacteria. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Talk to your care team about the vaccines you'll need to receive before starting ravulizumab. • If you have not been vaccinated and ravulizumab must be started right away, your care team will likely start you on antibiotics. • Meningococcal vaccines do not prevent all meningococcal infections. • Your care team 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 dose of ravulizumab. Your risk of meningococcal infection may continue for several months after your last dose of ravulizumab. It is important to show this card to any care team that treats you. This will help them diagnose and treat you quickly. <p>Call your care team or get emergency medical care right away if you get any of these signs and symptoms:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Fever with high heart rate • Fever with a rash • Fever and headache • Confusion • Muscle aches with flu-like symptoms • Headache with nausea or vomiting • Headache with stiff neck or stiff back • Eye sensitivity to light

<p>Other Serious Infections</p>	<p>Description: Ravulizumab may also increase the risk of other types of serious infections caused by encapsulated bacteria, including <i>Streptococcus pneumoniae</i>, <i>Haemophilus influenzae</i>, and <i>Neisseria gonorrhoeae</i>.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Talk to your care team about the vaccines you should receive. • Certain people may be at risk of serious infections with gonorrhea. Talk to your care team about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
<p>Headache</p>	<p>Description: Headaches are pain in your head that can vary in intensity, frequency, and location.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches. • Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches. • Apply a cold or warm compress to your forehead or neck to help ease headache pain. • Get adequate sleep (7 to 8 hours per night) and establish a regular sleep schedule. • Limit caffeine intake. • Your care team may recommend medicine for headaches. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Severe headache • More frequent or worsening headaches • Dizziness or feeling faint • Confusion • Changes in vision

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Red Blood Cell Breakdown (Hemolysis)	<p>If you have PNH, your care team will need to monitor you closely for at least 16 weeks after stopping treatment for signs of worsening PNH or problems related to breakdown of your red blood cells.</p> <ul style="list-style-type: none"> Drop in your red blood cell count Tiredness Blood in your urine Stomach-area (abdomen) pain Shortness of breath Blood clots Trouble swallowing Erectile dysfunction (ED)
Thrombotic Microangiopathy (TMA)	<p>If you have aHUS, your care team 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 TMA.</p> <ul style="list-style-type: none"> Confusion or loss of consciousness Seizures Chest pain (angina) Difficulty breathing Blood clots or stroke
Infusion-Related Reactions	<ul style="list-style-type: none"> Chills or shaking Itching, rash, or flushing Trouble breathing, wheezing, or tongue swelling Dizziness or feeling faint Feeling of impending doom Fever of 100.4°F (38°C) or higher New or severe pain in your back or neck

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- It is **not known if ravulizumab can harm an unborn baby**.
 - Pregnancy Registry: There is a registry for people who are pregnant who take ravulizumab. The purpose of this registry is to check the health of the pregnant person and their baby. If you are pregnant or become pregnant while taking ravulizumab, talk to your care team about how you can join this pregnancy registry. You may contact the registry at 1-833-793-0563 or www.UltomirisPregnancyStudy.com to enroll.
- Do NOT breastfeed** during treatment and for 8 months after your last dose of ravulizumab.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Ravulizumab is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS).** Before you can receive ravulizumab, your care team must:
 - Enroll in the ULTOMIRIS and SOLIRIS 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 ravulizumab right away and you are not up to date on your vaccines
 - Give you a Patient Safety Card about your risk of meningococcal infection, as discussed above
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

Updated Date: April 28, 2026

Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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