

ULTOMIRIS® REMS

Prescriber Safety Brochure

This brochure provides information on:

- The risk of meningococcal infection
- Patient meningococcal vaccination recommendations
- Monitoring Patients
- Counseling and providing your patients with a Patient Safety Brochure and Patient Safety Card

Risk of Serious Meningococcal Infections

- Life-threatening meningococcal infections/sepsis have occurred in patients treated with ULTOMIRIS.

Immunization

- **Immunize all patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS**, unless the risks of delaying ULTOMIRIS therapy outweigh the risks of developing a meningococcal infection.
- **Provide 2 weeks of antibacterial drug prophylaxis to patients if ULTOMIRIS must be initiated immediately and vaccines are administered less than two weeks before starting ULTOMIRIS therapy.**
- Do not initiate ULTOMIRIS therapy in patients with unresolved serious *Neisseria meningitidis* infection or who are not currently vaccinated, unless the risks of delaying ULTOMIRIS treatment outweigh the risk of developing a meningococcal infection.
- If urgent ULTOMIRIS therapy is indicated in an unvaccinated patient, administer meningococcal vaccines(s) as soon as possible.
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections.**
- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies. Revaccinate patients in accordance with ACIP recommendation, considering the duration of ULTOMIRIS therapy.

Monitoring Patients

- Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected.
- Consider discontinuation of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection.

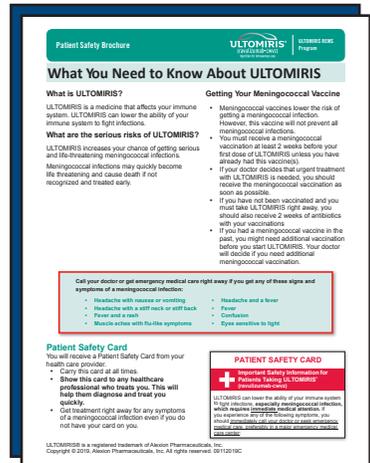
Patient Counseling

Counsel and provide your patients with both the **Patient Safety Brochure** and **Patient Safety Card**.

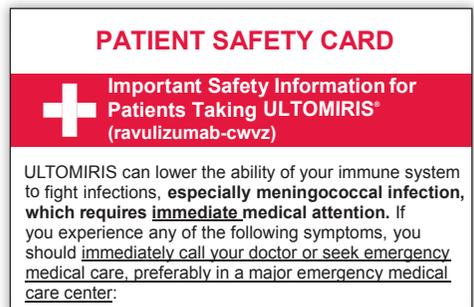
- Tell your patients about the risk of meningococcal infections and that this risk may continue for several months after the last dose of ULTOMIRIS.
- Instruct your patients to seek immediate medical attention if they develop any of the following symptoms:
 - Headache with nausea or vomiting
 - Headache with a stiff neck or stiff back
 - Fever and rash
 - Muscle aches with flu-like symptoms
 - Headache and a fever
 - Fever
 - Confusion
 - Eyes sensitive to light

Patient Safety Card

The card has important safety guidance for both patients and any healthcare provider that may see or treat your patient for medical care.



The image shows a Patient Safety Brochure for ULTOMIRIS. The title is "What You Need to Know About ULTOMIRIS". It is divided into two columns. The left column, titled "What is ULTOMIRIS?", explains that ULTOMIRIS is a medicine that affects the immune system and can lower the ability to fight infections. It also states that ULTOMIRIS increases the chance of getting serious and life-threatening meningococcal infections. The right column, titled "Getting Your Meningococcal Vaccine", lists several points: meningococcal vaccines lower the risk of getting a meningococcal infection but do not prevent all; patients must receive a meningococcal vaccination at least 2 weeks before the first dose of ULTOMIRIS; if a doctor decides that urgent treatment with ULTOMIRIS is needed, patients should get the meningococcal vaccination as soon as possible; if not vaccinated, patients should take ULTOMIRIS right away and receive 2 weeks of antibiotics; and if vaccinated, patients might need additional vaccination in the past, so they should consult their doctor. A red-bordered box contains a call to action: "Call your doctor or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:" followed by a list of symptoms: headache with nausea or vomiting, headache with a stiff neck or stiff back, fever and rash, muscle aches with flu-like symptoms, headache and a fever, fever, confusion, and eyes sensitive to light. At the bottom, there is a "Patient Safety Card" section with a red cross icon and the text "Important Safety Information for Patients Taking ULTOMIRIS". It repeats the warning about the immune system and provides instructions to call the doctor or seek emergency care if symptoms appear. The ULTOMIRIS logo and "increased risk of meningitis" are also visible.



The image shows a Patient Safety Card for ULTOMIRIS. It has a red header with the text "PATIENT SAFETY CARD" and "Important Safety Information for Patients Taking ULTOMIRIS® (ravulizumab-cwvz)". Below the header is a white cross icon. The main text reads: "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:"

- Discuss the importance and the proper use of this safety card with every patient.
- **Tell your patients to carry this card at all times, including for 8 months after the patient discontinues treatment with ULTOMIRIS.**
- Instruct patients to show the card to any healthcare professional involved in their care.

ULTOMIRIS REMS (Risk Evaluation and Mitigation Strategy)

A REMS is a program required by the FDA to manage known or potential serious risk associated with a drug program. ULTOMIRIS is available only through a restricted program under a REMS. Healthcare providers who prescribe ULTOMIRIS must be specially certified. Certification consists of review of REMS education materials and enrollment in the ULTOMIRIS REMS program.



Visit www.ultomirisrems.com or call 1-888-765-4747 to learn more about the **ULTOMIRIS REMS**. Enrollment can also be completed online at www.ultomirisrems.com.

Indication and Usage

ULTOMIRIS is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

ULTOMIRIS is indicated for the treatment of adult and pediatric (one month and older) patients with atypical Hemolytic Uremic Syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Limitation of Use

ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Adverse Event Experiences

To report any suspected adverse event experience, contact Alexion Pharmaceuticals Inc. at 1.844.259.6783 or report to the FDA at 1.800.FDA.1088.

This guide does not provide all risk information for ULTOMIRIS.

Please see full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infection for more detailed safety information.

