

### **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.

## **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 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.

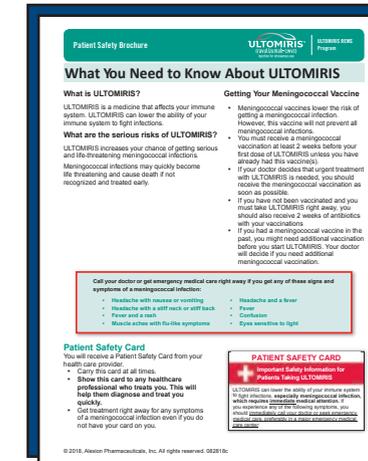
## Monitoring Patients

- 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 weeks 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.



- Discuss the importance and the proper use of this safety card with every patient.
- Tell your patients to carry this card at all times.
- 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](http://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](http://www.ultomirisrems.com).

## Indication and Usage

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

## Limitation of Use

ULTOMIRIS is not indicated in patients less than 18 years old.