ALEXION®
AstraZeneca Rare Disease

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

INDICATION & IMPORTANT SAFETY INFORMATION FOR ULTOMIRIS® (ravulizumab-cwvz)

INDICATION

Generalized Myasthenia Gravis (gMG)

ULTOMIRIS is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening meningococcal infections/sepsis have occurred in patients treated with ULTOMIRIS. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.**
- **Immunize 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 risk of developing a meningococcal infection. See Warnings and Precautions for additional guidance on the management of the risk of meningococcal infection.**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.**

ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the ULTOMIRIS REMS, prescribers must enroll in the program. Enrollment in the ULTOMIRIS REMS program and additional information are available by telephone: 1-888-765-4747 or at www.ultomirisrems.com.

Contraindications

- Patients with unresolved *Neisseria meningitidis* infection.
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying ULTOMIRIS treatment outweigh the risks of developing a meningococcal infection.

Please see Important Safety Information continued on page 2 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

IMPORTANT SAFETY INFORMATION FOR ULTOMIRIS® (ravulizumab-cwvz) (cont'd)

Warnings and Precautions

Serious Meningococcal Infections

Risk and Prevention

Life-threatening meningococcal infections have occurred in patients treated with ULTOMIRIS. The use of ULTOMIRIS increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis). Meningococcal disease due to any serogroup may occur.

Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without history of meningococcal vaccination at least 2 weeks prior to the first dose of ULTOMIRIS. If ULTOMIRIS must be initiated immediately in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide 2 weeks of antibacterial drug prophylaxis.

In clinical studies, 2 adult patients with gMG were treated with ULTOMIRIS less than 2 weeks after meningococcal vaccination. All of these patients received antibiotics for prophylaxis of meningococcal infection until at least 2 weeks after meningococcal vaccination. The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving ULTOMIRIS have not been established. Consider discontinuation of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection.

REMS

Under the ULTOMIRIS REMS, prescribers must enroll in the program due to the risk of meningococcal infections. Prescribers must counsel patients about the risk of meningococcal infection/sepsis, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines.

Other Infections

Patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. If ULTOMIRIS is administered to patients with active systemic infections, monitor closely for worsening infection.

Thromboembolic Event Management

The effect of withdrawal of anticoagulant therapy during treatment with ULTOMIRIS has not been established. Treatment should not alter anticoagulant management.

Infusion-Related Reactions

Administration of ULTOMIRIS may result in infusion-related reactions including anaphylaxis and hypersensitivity reactions. In clinical trials, infusion-related reactions occurred in approximately 1% of patients treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, elevation in blood pressure and limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. Interrupt infusion and institute supportive measures if signs of cardiovascular instability or respiratory compromise occur.

ADVERSE REACTIONS

Most common adverse reactions in adult patients with gMG (incidence ≥10%) were diarrhea and upper respiratory tract infection. Serious adverse reactions were reported in 20 (23%) of patients treated with ULTOMIRIS and in 14 (16%) patients receiving placebo. The most frequent serious adverse reactions were infections reported in at least 8 (9%) patients treated with ULTOMIRIS and in 4 (4%) patients treated with placebo. Of these infections, one fatal case of COVID-19 pneumonia was identified in a patient treated with ULTOMIRIS and one case of infection led to discontinuation of ULTOMIRIS.

DRUG INTERACTIONS

Plasma Exchange, Plasmapheresis, and Intravenous Immunoglobulins

Concomitant use of ULTOMIRIS with plasma exchange (PE), plasmapheresis (PP), or intravenous immunoglobulin (IVIg) treatment can reduce serum ravulizumab concentrations and requires a supplemental dose of ULTOMIRIS.

Neonatal Fc Receptor Blockers

Concomitant use of ULTOMIRIS with neonatal Fc receptor (FcRn) blockers (e.g., efgartigimod) may lower systemic exposures and reduce effectiveness of ULTOMIRIS. Closely monitor for reduced effectiveness of ULTOMIRIS.

Please see Important Safety Information continued on page 1 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

NEW
Patient Checklist

ONESOURCE® Personalized Patient Support from Alexion

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

This checklist contains steps to initiate a patient on ULTOMIRIS® (ravulizumab-cwvz) after the treatment decision has been made.

☐ **Enroll in our REMS program (required)**

Due to the risk of meningococcal infections, prescribers must enroll in our Risk Evaluation and Mitigation Strategy (REMS) program to obtain ULTOMIRIS. Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccine(s). Call Customer Operations at **1-888-765-4747** or visit **www.ultomirisrems.com** to learn more and enroll.

☐ **Consider completing the Neurology ULTOMIRIS Patient & Prescriber START Form to get your patients started**

If completing, provider and patient signature is required

OneSource™ may be able to assist your patient with:

- Education
- Health Insurance Navigation
- Community Connections
- Ongoing Support
- Financial Assistance
- Vaccination Support

☐ **Confirm patient has prescriptions for required meningococcal vaccinations**

a. Patient can be vaccinated at
   i. Primary care office
   ii. Local pharmacy
   iii. Local hospital
   iv. Health department
   v. Travel clinic

Immunize patients with both types of meningococcal vaccines at least 2 weeks before starting treatment with ULTOMIRIS[1,a]

The 2022 Advisory Committee on Immunization Practices (ACIP) recommends the following meningococcal vaccination regimens for adult patients (aged ≥19 years) with persistent complement component deficiency or in patients receiving complement inhibitors, including patients receiving ULTOMIRIS[2,b]

MenACWY		MenB-4C		MenB-FHbp
2 DOSES	+	**2 DOSES**	OR	**3 DOSES**
At least 8 weeks apart		At least 1 month apart		0, 1-2, and 6 months[c]
Single booster dose every 5 years if risk remains		Single booster dose 1 year following completion of primary series and every 2 to 3 years if risk remains		
		MenB vaccines are not interchangeable		
		You must receive the same product for all doses		

[a]Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of ULTOMIRIS. If urgent ULTOMIRIS therapy is indicated in an unvaccinated patient, the meningococcal vaccines should be administered as soon as possible and patients should receive antibacterial drug prophylaxis from time of ULTOMIRIS initiation until 2 weeks after vaccination, in order to minimize the risk of infection in unvaccinated, unprotected patients. [b]Please refer to the most up-to-date ACIP recommendations for the most current and complete information for meningococcal vaccination in persons with persistent complement component deficiencies and patients treated with complement inhibitors, such as ULTOMIRIS. [c]For MenB-FHbp, if dose 2 was administered at least 6 months after dose 1, dose 3 is not needed.[2]

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☐ **Consider identifying preferred site of care for infusion on START Form**

a. Prescriber's office
b. Home infusion
c. Infusion center

☐ **Encourage completion of gMG assessment tools[3]**

a. Patient-reported
   i. MG-ADL
b. Physician-reported
   ii. QMG

☐ **Confirm ULTOMIRIS order has been placed**

An Alexion Customer Operations Representative will facilitate order processing and delivery.

☐ **Refer to sample letter of medical necessity should a payer request one**

Alexion Patient Services is here to help you and your patients.

OneSource™ is a complimentary, personalized patient support program tailored to the specific needs of adults living with anti-AChR antibody-positive gMG.

For more information, please visit **AlexionOneSource.com**, or contact us at

1-888-765-4747 **OneSource@alexion.com**

Please see Important Safety Information on pages 1 and 2 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

AChR, acetylcholine receptor**; gMG**, generalized myasthenia gravis; **MG-ADL**, myasthenia gravis activities of daily living; **QMG**, quantitative myasthenia gravis.

References: 1. Ultomiris. Prescribing information. Alexion Pharmaceuticals Inc. **2.** Murthy N, et al. *Ann Intern Med.* 2022;175(3):432-443. **3.** Resources for professionals. Myasthenia Gravis Foundation of America Website. Accessed March 23, 2022. https://myasthenia.org/professionals/resources-for-professionals

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