INDICATION

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

SELECT 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.**

Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS REMS.

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

ULTOMIRIS® was proven to deliver improvement in activities of daily living in CHAMPION-MG[1,2]

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

CHAMPION-MG was a Phase 3, randomized, double-blind, placebo-controlled trial with an open-label extension (OLE). Patients were randomized to receive either ULTOMIRIS (n=86) or placebo (n=89) for 26 weeks and were subsequently allowed to enter the OLE period for up to 4 years[1-3]

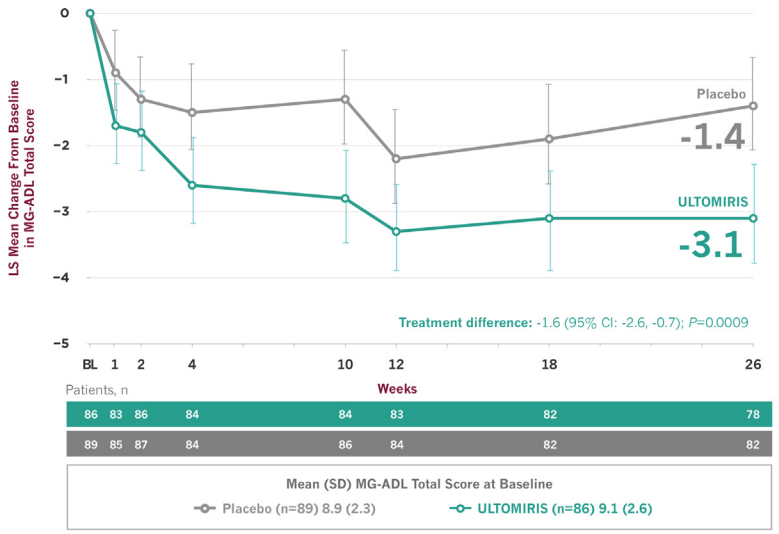
More than 90% of patients had MGFA class II or III gMG with mild or moderate muscle weakness at baseline.[1,3,4] Approximately 90% of patients were taking an immunosuppressive therapy (IST) at baseline across both treatment arms.[1,3,4,a]

- Patients on concomitant ISTs were required to be on stable doses throughout the course of the study, and those medications could be adjusted as necessary during the OLE.[3]

Among patients in the ULTOMIRIS treatment arm,

Improvements in MG-ADL total scores from baseline were observed within 1 week of treatment and were sustained through Week 26 of treatment.[1,b]

ULTOMIRIS demonstrated efficacy vs placebo at Week 26 (-3.1 vs -1.4, respectively [*P*=0.0009])[1,3]



More than **2x** greater improvement vs placebo

CHAMPION-MG STUDY LIMITATIONS: Data shown are LS means and 95% confidence intervals (CIs), using a mixed model for repeated measures; 95% CIs were not adjusted for multiplicity.[1,3]

Time to response was part of the planned efficacy analysis, but the primary endpoint was at Week 26. Therefore, results should be interpreted with caution.

BL, baseline; gMG, generalized myasthenia gravis; LS, least squares; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; SD, standard deviation.

[a]Immunosuppressive agents include glucocorticoids, azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate mofetil, or tacrolimus.[4]

[b]The MG-ADL is a categorical scale that assesses the impact on daily function of 8 signs or symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. The total score ranges from 0 to 24, with the higher scores indicating more impairment.[1]

SELECT IMPORTANT SAFETY INFORMATION

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.

Safety was evaluated for 26 weeks in CHAMPION-MG[1,3]

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

Adverse reactions reported in ≥5% and at greater frequency than placebo in ULTOMIRIS®-treated patients[1]

Adverse Reactions	ULTOMIRIS (n=86), n (%)	Placebo (n=89), n (%)
GASTROINTESTINAL DISORDERS		
Diarrhea	13 (15)	11 (12)
Abdominal pain	5 (6)	0
INFECTIONS AND INFESTATIONS		
Upper respiratory tract infection	12 (14)	7 (8)
Urinary tract infection	5 (6)	4 (4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
Back pain	7 (8)	5 (6)
NERVOUS SYSTEM DISORDERS		
Dizziness	8 (9)	3 (3)

- Serious adverse reactions were reported in 20 (23%) patients with gMG receiving ULTOMIRIS and in 14 (16%) patients receiving placebo[1]
- 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[1]
- 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[1]
- The most frequent adverse reactions occurring in ≥10% of patients taking ULTOMIRIS were diarrhea and upper respiratory tract infection[1]

gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

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. Patients who initiate ULTOMIRIS treatment less than 2 weeks after receiving meningococcal vaccine(s) must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.

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.

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

Meet Madison, a social worker focused on her career[a]

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

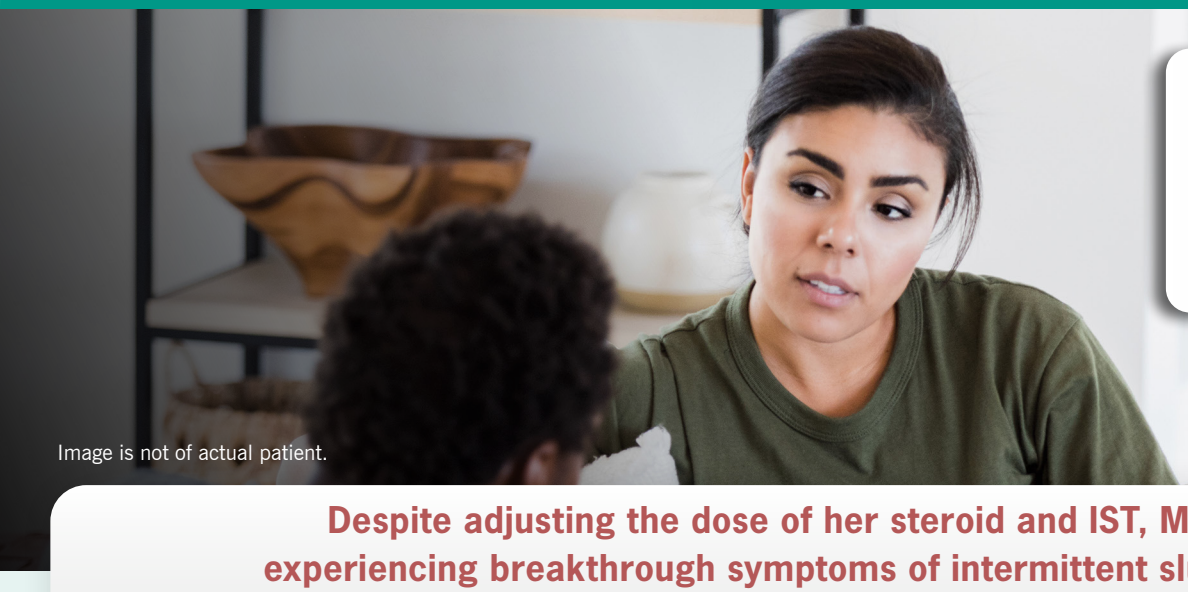


Image is not of actual patient.

Age: 32 years

Duration of disease: 8 months; treatment initiated upon diagnosis

Past hobbies: Bike riding and hiking

[a]Patient case is fictitious and is not intended for diagnosis and treatment purposes.

Despite adjusting the dose of her steroid and IST, Madison is still experiencing breakthrough symptoms of intermittent slurring of speech, increased shortness of breath, and lower limb paresis

DISEASE PROFILE

- Rapid progression from oMG to gMG required steroids and ISTs to manage symptoms
- Clinical classification of MGFA class IIIa

CURRENT gMG REGIMEN

- Prednisone 40 mg once daily
  - Initially on low-dose steroids and IST; increased steroids to 80 mg per day, then reduced to 40 mg per day due to steroid-related ARs and unable to reduce further
- Azathioprine 150 mg once daily
- Pyridostigmine 60 mg four times daily

FAMILY MEDICAL HISTORY

- Osteoporosis and diabetes mellitus

CURRENT MG-ADL DOMAINS[5]

Intermittent slurring or nasal speech	+1
Normal chewing	+0
Normal swallowing	+0
Shortness of breath with exertion	+1
Extra effort while brushing teeth, but no rest periods needed	+1
Moderate impairment to rise from chair, requiring use of arms	+2
Occasional double vision	+1
No eyelid droop	+0
CURRENT MG-ADL TOTAL SCORE	**6**

Madison is experiencing steroid-related ARs including weight gain and increased acne. She and her physician are also concerned about future comorbidities associated with long-term steroid use[6]

AR, adverse reaction; IST, immunosuppressive therapy; gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; oMG, ocular myasthenia gravis.

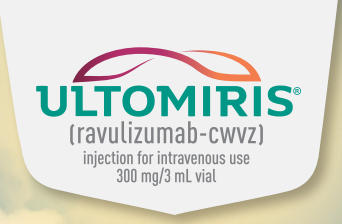
SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS, (continued)

ULTOMIRIS REMS

Due to the risk of meningococcal infections, ULTOMIRIS is available only through a restricted program under a REMS called ULTOMIRIS REMS.

Why consider ULTOMIRIS® for Madison?



Madison fits the eligibility criteria
For the CHAMPION-MG trial, >90% of patients had MGFA class II or III gMG with mild or moderate muscle weakness at baseline[3,4]

Madison hopes to see an improvement in her ability to perform activities of daily living
ULTOMIRIS offers adult patients more than 2x greater improvement in MG-ADL total score from baseline at Week 26 vs placebo (-3.1 vs -1.4, respectively [*P*=0.0009])[1,3,a]

Madison wants to minimize disruptions to her life caused by frequent infusions
ULTOMIRIS may be right for her, as treatment is dosed at predictable 8-week intervals starting 2 weeks after an initial loading dose, and only requires 6 to 7 maintenance infusions per year[1]

Madison and her physician are concerned about her steroid-related ARs and future comorbidities she may develop
Given her family history of diabetes and osteoporosis, she may be at a higher risk[6,7]

If you have a patient like Madison who you think could be right for ULTOMIRIS, get them started at gMGStartForm.com.

[a]Based on the MG-ADL, a categorical scale that assesses the impact on daily function of 8 signs or symptoms that are typically affected in gMG.[1]

AR, adverse reaction; gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS, (continued)

ULTOMIRIS REMS, (continued)

Under the ULTOMIRIS REMS, prescribers must enroll in the program. 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.

Additional information on the REMS requirements is available at www.ultomirisrems.com or 1-888-765-4747.

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.

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

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS, (continued)

Infusion-Related Reactions

Intravenous administration of ULTOMIRIS may result in systemic 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, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS infusion and institute appropriate supportive measures.

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.

Scan QR code or visit the link (https://bit.ly/3KEpmzp)

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

Image is not of actual patient.

Help your adult patients with anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) get started on ULTOMIRIS®

Fill out the Patient & Prescriber Start Form

Order the meningococcal vaccination series, provide a prescription for ULTOMIRIS, and enroll your patient in support services, all in one place at gMGStartForm.com.

Talk to your patients about OneSource™

OneSource is a comprehensive, complimentary, and personalized patient support program offered by Alexion that provides education, health insurance navigation, community connections, and ongoing support to patients and their caregivers. Your patients can find a local Patient Education Manager in their area by visiting alexiononesource.com/pem-finder.

Enroll in the ULTOMIRIS Risk Evaluation and Mitigation Strategy (REMS) program

Due to the risk of meningococcal infections, ULTOMIRIS is available only through a restricted program under a REMS called ULTOMIRIS REMS.

Scan to enroll in the ULTOMIRIS REMS Program and see additional requirements. You can also call 1-888-765-4747 for more information.

References: 1. ULTOMIRIS. Prescribing information. Alexion Pharmaceuticals, Inc. **2.** Meisel A, et al. *J Neurol*. 2023;270(8):3862-3875. **3.** Data on file. Alexion Pharmaceuticals, Inc. **4.** Vu T, et al. *NEJM Evid*. 2022;1(5):1-22. **5.** Myasthenia.org. MG Activities of Daily Living (MG-ADL). UT Southwestern Medical Center, Dallas, 1997. **6.** Johnson S, et al. *Med Sci Monit*. 2021;27:e933296. **7.** Sathasivan S. *Nat Clin Pract Neurol*. 2008;4(6):317-327.

ONESOURCE® Personalized Patient Support from Alexion

ALEXION® AstraZeneca Rare Disease