For your adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive

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

Explore how ULTOMIRIS® provides 8 WEEKS of freedom for gMG patients[1]

Switching to ULTOMIRIS provides adult patients once-every-8-week maintenance dosing starting 2 weeks after an initial loading dose[1]

Mike, a generalized myasthenia gravis patient who switched from eculizumab to ULTOMIRIS, enjoys travel with his wife. With the predictable ULTOMIRIS dosing schedule, he has the freedom to schedule the long cruises he loves within the 8 weeks between infusions.

Mike has received compensation from Alexion Pharmaceuticals, Inc. and has a relative who works for Alexion.

Mike, living with gMG

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ULTOMIRIS, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [*see Warnings and Precautions (5.1)*] Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.**
- **Patients receiving ULTOMIRIS are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious 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 and SOLIRIS REMS [*see Warnings and Precautions (5.2)*].

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

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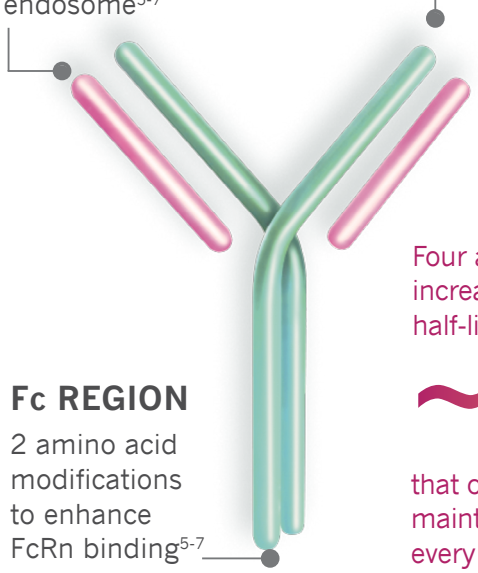
The first and only long-acting complement C5 inhibitor, offering immediate, complete, and sustained complement inhibition[1-4]

The precise mechanism by which ULTOMIRIS® exerts its therapeutic effect is not known.[1]

Fab REGIONS

2 amino acid modifications to promote the dissociation of C5 from ULTOMIRIS in the endosome[5-7]



Fc REGION

2 amino acid modifications to enhance FcRn binding[5-7]

Four amino acid changes increased the ULTOMIRIS half-life to

~4x

that of eculizumab, enabling maintenance dosing once every 8 weeks[1,6,a]

ULTOMIRIS is built on the foundation of eculizumab but is designed for extended inhibition and elimination of C5 through lysosomal degradation[5,6]

Review the **ULTOMIRIS mechanism of action** (bit.ly/3PhvMbg)

ADVANTAGES OF ULTOMIRIS MODIFICATIONS FROM ECULIZUMAB[5,6]:

ULTOMIRIS is less likely to be degraded along with C5

ULTOMIRIS is more likely to be recycled back into circulation multiple times, increasing and extending its half-life

"My neurologist said instead of having an infusion every two weeks, it will be every 8 weeks, and I said, 'Great! That's what I want!'"

- Mike, a patient living with gMG

Watch Mike's story

bit.ly/4c924yV

[a]The mean (SD) terminal elimination half-life and clearance of ULTOMIRIS in adult patients with gMG are 56.6 (8.36) days and 0.08 (0.02) liters/day, respectively. The half-life of eculizumab is approximately 11.25 to 17.25 days.[1,8]

Fab, fragment antigen-binding; Fc, fragment crystallizable; FcRn, neonatal Fc receptor; MOA, mechanism of action.

IMPORTANT SAFETY INFORMATION, (continued)

CONTRAINDICATIONS

- Initiation in patients with unresolved serious *Neisseria meningitidis* infection.

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A predictable, once-every-8-week dosing schedule starting 2 weeks after an initial loading dose[1]

Give patients the dosing schedule that delivers 8 weeks of freedom between infusions (compared to one maintenance infusion every 2 weeks with eculizumab).[1,8]

6-7 infusions annually

- ULTOMIRIS® offers **only 6-7 infusions per year** after an initial loading dose, giving patients an additional 6 weeks between infusions and less time at the infusion center (average infusion time is less than an hour)[1,8]
  - Patients currently experiencing 26 infusions a year with eculizumab can expect only 6-7 infusions a year after switching treatment[1,8]

- When switching treatment from eculizumab to ULTOMIRIS, administer the loading dose of ULTOMIRIS 2 weeks after the last eculizumab maintenance infusion (or 1 week after the last eculizumab induction infusion). Then administer ULTOMIRIS maintenance doses **once every 8 weeks starting 2 weeks after loading dose** administration[1]

bit.ly/3Vb3bZ3

Learn more about the steps to switch your patients to ULTOMIRIS

- In clinical trials after the administration of ULTOMIRIS, the IV line was flushed with 0.9% sodium chloride.[9] Additional dosing considerations include:
  - With weight-based dosing, make sure to weigh patients before each infusion[1]
  - Plasma exchange (PE), plasmapheresis (PP), and intravenous immunoglobulin (IVIg) can decrease serum ULTOMIRIS concentrations. If dosing after PE, PP, or IVIg, a supplemental dose of ULTOMIRIS is needed[1]

bit.ly/43gRrGm

Learn more about ULTOMIRIS and visit our dosing calculator

IMPORTANT SAFETY INFORMATION, (continued)
WARNINGS AND PRECAUTIONS
Serious Meningococcal Infections

ULTOMIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

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

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ULTOMIRIS® is proven to deliver improvement in activities of daily living[1]

CHAMPION-MG was a Phase 3, randomized, double-blind, placebo-controlled trial. Patients were randomized to receive either ULTOMIRIS (n=86) or placebo (n=89) for 26 weeks.[1,10]

More than 2x greater improvement in MG-ADL total score vs placebo at Week 26[1]

Change is from baseline at Week 26 vs placebo (-3.1 for ULTOMIRIS vs -1.4 for placebo [*P*=0.0009]).[1,9,a]

3.5x greater improvement shown in the key secondary endpoint, QMG total score at Week 26[1]

Change is from baseline at Week 26 vs placebo (-2.8 points for ULTOMIRIS vs -0.8 points for placebo [*P*=0.0009]).[1,9,b]

The most common side effects

reported in ≥10% of people taking ULTOMIRIS were diarrhea and upper respiratory tract infection.[1]

Additionally, ULTOMIRIS patients were allowed to enter the OLE for up to 4 years. Learn more about ULTOMIRIS' CHAMPION-MG study and the OLE data (bit.ly/3TcqHC9).

"Every year, my wife and I take all 15 of our grandchildren for what we call Grandparents' Weekend...I'm very happy that I can have Grandparents' Weekend like I used to."

- Mike, a patient living with gMG

[a]Mean (SD) MG-ADL total score at baseline was 8.9 (2.3) for placebo (n=89) and 9.1 (2.6) for ULTOMIRIS (n=86).[9]
[b]Mean (SD) QMG total score at baseline was 14.5 (5.3) for placebo (n=89) and 14.8 (5.2) for ULTOMIRIS (n=86).[9]
MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; QMG, Quantitative Myasthenia Gravis.

IMPORTANT SAFETY INFORMATION, (continued)
WARNINGS AND PRECAUTIONS, (continued)
Serious Meningococcal Infections, (continued)

Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.

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

"I was also connected with the Alexion Patient Support Team, OneSource. They were so helpful in what could be a very confusing process."

- Mike, a patient living with gMG

Alexion OneSource™ is ready to help your patients and your practice to ensure a seamless switch

OneSource is a comprehensive, complimentary, and personalized patient support program that is offered by Alexion to help with a variety of your patients' needs, from diagnosis through treatment.

- Navigating the CoPay Program, where patients may **pay as little as $0**[a]
- Explaining access and insurance coverage for ULTOMIRIS®
- Arranging the required meningococcal vaccinations
- Locating infusion centers or other nearby options
- Connecting gMG patients in the community and more

Get started with OneSource

bit.ly/3Ti2iLF

$0 out-of-pocket costs for eligible patients

1-888-765-4747 • OneSource@alexion.com
AlexionOneSource.com/Ultomiris

ONESOURCE®
Personalized Patient Support from Alexion

bit.ly/49NiQSx

ALEXION ACCESS NAVIGATOR

Access Navigator is a dedicated resource website for US healthcare professionals and their offices that contains downloadable access and reimbursement materials for ULTOMIRIS in gMG.

[a]The Alexion OneSource CoPay Program provides financial assistance by covering up to $15,000 US dollars per calendar year for eligible patients' out-of-pocket medication and infusion costs associated with ULTOMIRIS.

IMPORTANT SAFETY INFORMATION, (continued)
WARNINGS AND PRECAUTIONS, (continued)
Serious Meningococcal Infections, (continued)

Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ULTOMIRIS. The benefits and risks of treatment with ULTOMIRIS, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

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

IMPORTANT SAFETY INFORMATION, (continued)

WARNINGS AND PRECAUTIONS, (continued)

Serious Meningococcal Infections, (continued)

Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection depending on the risks of interrupting treatment in the disease being treated.

ULTOMIRIS and SOLIRIS REMS

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

Prescribers must enroll in the REMS, counsel patients about the risk of serious meningococcal infection, provide patients with the REMS educational materials, assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of ULTOMIRIS. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently, and the patient is not up to date with both meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of ULTOMIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card at all times during and for 8 months following ULTOMIRIS treatment.

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

Other Infections

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

ULTOMIRIS blocks terminal complement activation; therefore, 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*. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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 systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions. In clinical trials, infusion-related reactions occurred in approximately 1 to 7% of patients, including lower back pain, abdominal pain, muscle spasms, drop or elevation in blood pressure, rigors, limb discomfort, drug hypersensitivity (allergic reaction), and dysgeusia (bad taste). These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS and institute appropriate supportive measures.

References: 1. ULTOMIRIS. Prescribing information. Alexion Pharmaceuticals, Inc. **2.** Kulasekararaj AG, et al. *Blood.* 2019;133(6):540-549. **3.** Lee JW, et al. *Blood.* 2019;133(6):530-539. **4.** Vu T, et al. *J Neurol.* 2023;(270):3129-3137. **5.** Sheridan D, et al. *PLoS One.* 2018;13(4):e0195909. **6.** Röth A, et al. *Blood Adv.* 2018;2(17):2176-2185. **7.** Rother RP, et al. *Nat Biotechnol.* 2007;25(11):1256-1264. **8.** SOLIRIS. Prescribing information. Alexion Pharmaceuticals, Inc. **9.** Data on file. Alexion Pharmaceuticals, Inc. **10.** Meisel A, et al. *J Neurol.* 2023;270(8):3862-3875.

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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.

USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ULTOMIRIS during pregnancy. Healthcare providers and patients may call 1-833-793-0563 or go to www.UltomirisPregnancyStudy.com to enroll in or to obtain information about the registry.

To report SUSPECTED ADVERSE REACTIONS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION

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

bit.ly/3TyoWkk

Discuss transitioning to ULTOMIRIS® with your eculizumab patients and visit UltomirisHCP.com/gMG to learn more about ULTOMIRIS.

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

Scan QR code or visit the link to see the full Prescribing Information: UltomirisHCP.com/PI

ALEXION® AstraZeneca Rare Disease

ONESOURCE® Personalized Patient Support from Alexion

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