For your adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive[1]

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

Can ULTOMIRIS® help with concomitant corticosteroid use in your anti-AChR antibody-positive gMG patients?

Jesse, *a patient living with gMG.*

Jesse has received compensation from Alexion Pharmaceuticals, Inc.

It is not known if ULTOMIRIS is safe and effective for the treatment of gMG in children.[1]

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

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.

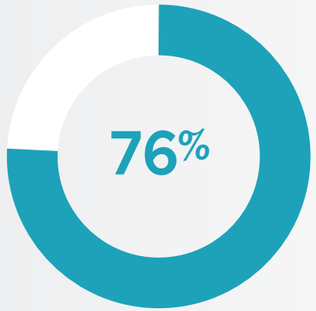
- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on 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.

Are conventional treatments working for your patients?[2]

Long-term, high-dose corticosteroid use is prevalent among patients with gMG[3]



of gMG patients (n/N=2033/2677) taking corticosteroids long term (>90 days) are on doses **>10 mg/day**[a]

gMG patients taking prednisone may be on doses **>30 mg/day**[b]

Cumulative corticosteroid exposure for many gMG patients can be as high as **>3500 mg/year**[4,c]

gMG, generalized myasthenia gravis.
[a]Data from a retrospective analysis of the IQVIA PharMetrics claims database from 1/1/2006 to 6/30/2022.[3]
[b]In the study, more than half of the patients with gMG had no corticosteroid use, ~17% had short corticosteroid use (≤90 days), and ~25% had long corticosteroid use (>90 days).[3]
[c]In the retrospective analysis, the proportion of patients on >10 mg/day of corticosteroids 12 months post-initiation were: 8% of patients (n=8) in the C5iT (complement component 5 inhibition therapy) group, 5% (n=8) in the FcRn-a (fragment crystallizable neonatal receptor alpha) group, and 13% (n=181) in the non-biologic group.[4]

Corticosteroids are a widely prescribed first-line immunotherapy, but come with risks[5-7]

These risks come with long-term use. It's important to consider dose reduction and discontinuation when treating with corticosteroids[5,6]

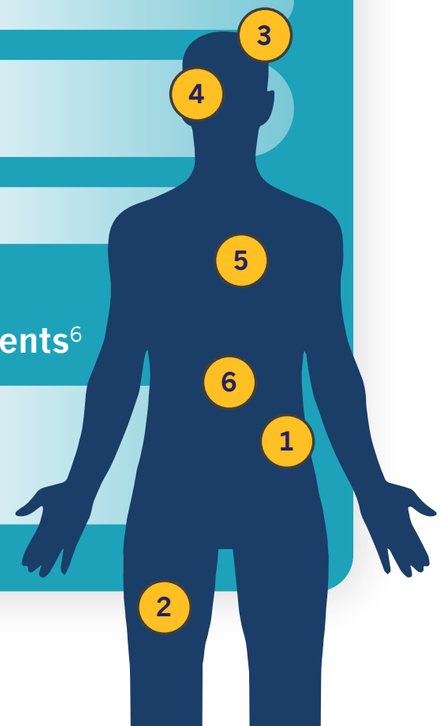
- Key guidelines recommend corticosteroid reduction to <5 mg/day, or elimination of corticosteroids, if nonsteroidal agents are available[8]

Potential limitations associated with long-term corticosteroid use include[6]

1. Metabolic conditions (weight gain, hyperglycemia, diabetes)
2. Osteoporosis
3. Neuropsychiatric symptoms
4. Ophthalmologic conditions
5. Cardiovascular issues (hypertension and arrhythmias)
6. Gastrointestinal issues

Additional systemic adverse events[6]

- Electrolyte imbalances
- Increased risk of infection
- Myopathy



CHAMPION-MG: The majority of patients were taking concomitant ISTs at baseline in this pivotal trial[1,9]

CHAMPION-MG was a randomized, multicenter, 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.[1,9]

~90%
taking an IST at baseline

In the CHAMPION-MG study, approximately **90% of patients were taking an IST at baseline** across both treatment arms.[1,9]

At the time of ULTOMIRIS initiation, in the ULTOMIRIS arm, approximately 65% of patients were receiving prednisone/corticosteroid therapies.[10]

- **The ISTs most commonly used (in ≥25% of total patients) at first dose of ULTOMIRIS in the ULTOMIRIS-treated arm were corticosteroids (65.1%) and mycophenolate mofetil (27.9%)[10]**

Patients in CHAMPION-MG were allowed to continue with their prior IST regimen until the OLE[11]

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)

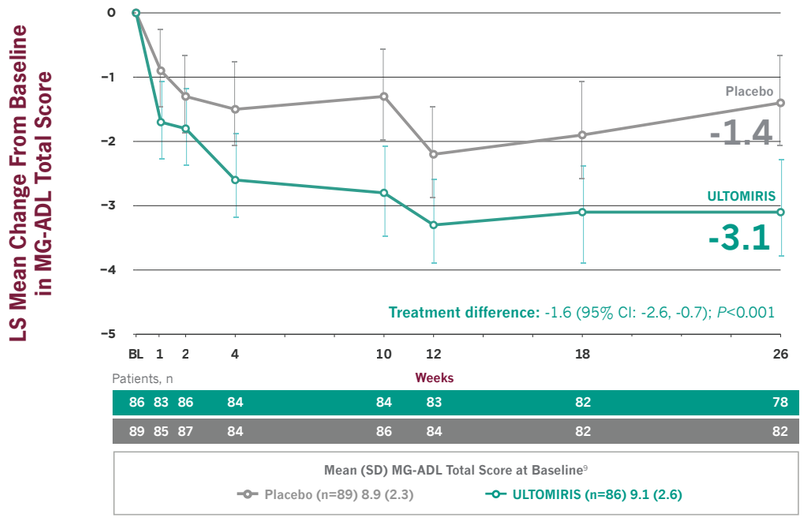
IST, immunosuppressive therapy.

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.

Proven to deliver improvement in MG activities of daily living (MG-ADL)[1]

Among patients in the ULTOMIRIS treatment arm,
Improvements in MG-ADL total scores were observed within 1 week of treatment and sustained through Week 26[1,a]

ULTOMIRIS demonstrated efficacy vs placebo at Week 26 (-3.1 vs -1.4, respectively [*P*<0.001])[1,9]



More than 2x greater improvement vs placebo[1,9]

CHAMPION-MG STUDY LIMITATIONS: Data shown are least-squares means and 95% confidence intervals (CIs), using a mixed model for repeated measures; 95% CIs were not adjusted for multiplicity.[1,9]

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.[1,9]

Reduction in MG-ADL total score seen in CHAMPION-MG was observed through Week 164 in the OLE period[11]

- The OLE period began following Week 26, when all patients received ULTOMIRIS, and results were observed through Week 164[11]

CHAMPION-MG OLE STUDY LIMITATION: Results or clinical outcomes should be interpreted with caution since the study was designed to evaluate safety and lacked a control group.

[a]MG-ADL is a patient-reported, 8-item assessment reflecting functional impairment of ocular, bulbar, respiratory, and limb symptoms with a maximum total score of 24.[12]

BL, baseline; LS, least squares; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Open-Label Extension Study: Safety Findings

Adverse reactions reported in ≥10% of patients treated with ULTOMIRIS® during the randomized controlled period or the open-label extension period up to data cutoff[11]

Adverse Reactions	ULTOMIRIS (n=169),[a] n (%)
INFECTIONS AND INFESTATIONS	
COVID-19	61 (36.1)
Urinary tract infection	21 (12.4)
Nasopharyngitis	20 (11.8)
NERVOUS SYSTEM DISORDERS	
Headache	39 (23.1)
GASTROINTESTINAL DISORDERS	
Diarrhea	29 (17.2)
Nausea	22 (13.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	
Arthralgia	23 (13.6)
Back pain	22 (13.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	
Fatigue	18 (10.7)
Dizziness	17 (10.1)

[a]Includes data available for all patients who received ≥1 dose of ULTOMIRIS in the randomized controlled period or the open-label extension period, up to Week 164 at data cutoff.[11]

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
Serious Meningococcal Infections

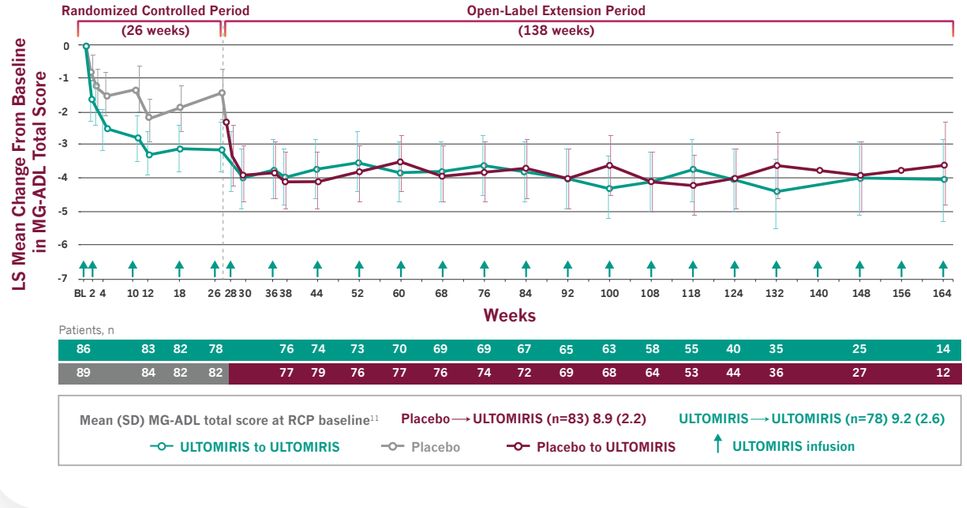
ULTOMIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred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

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.

Open-Label Extension Study: MG-ADL Total Score

Reduction in MG-ADL total score in CHAMPION-MG was observed in the OLE period through Year 3[13]



4-Point reduction in MG-ADL total scores[11]

ULTOMIRIS → ULTOMIRIS[11]
- LS mean change from RCP baseline at Week 164: -4.0 (95% CI: -5.3, -2.8)

Placebo → ULTOMIRIS[11]
- LS mean change from OLE baseline at Week 138: -2.1 (95% CI: -3.3, -0.9)

Reduction observed when switching from placebo to ULTOMIRIS following Week 26

- **2.1-point reduction after 138 weeks** (at Week 164 in CHAMPION-MG OLE)

The OLE period began following Week 26, when all patients received ULTOMIRIS and results were observed through Week 164. Patients who completed the RCP had the option to enter the OLE.[11]

BL, baseline; CI, confidence interval; LS, least squares; MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; RCP, randomized controlled period; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION
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*.

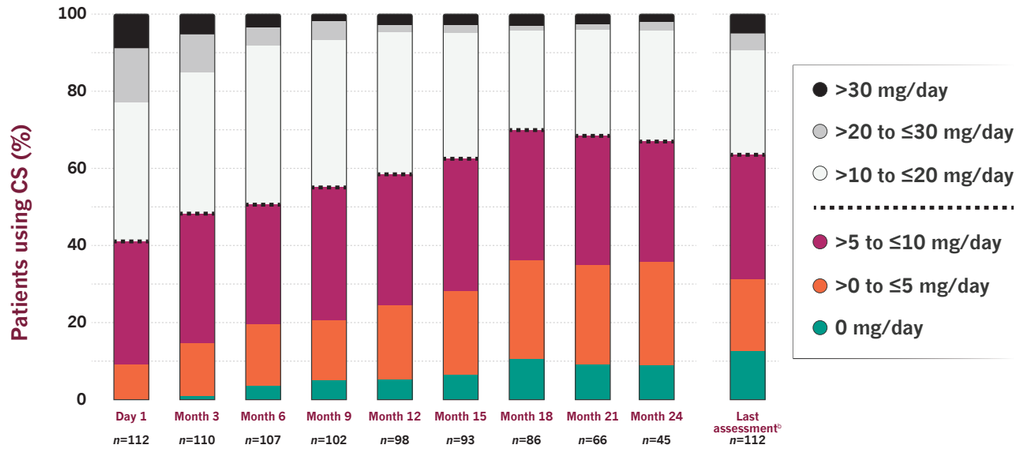
Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

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.

Post hoc analysis:
Corticosteroid use was observed in the OLE[11]

The change in corticosteroid use was assessed (n=112). Dose changes were only allowed in the OLE period beginning after Week 26 of CHAMPION-MG[11]

Changes in corticosteroid use in the OLE[a]



[a]All patients who were receiving corticosteroids at OLE start.[11]
[b]**Last assessment** is the final participant study visit during which outcomes were measured.[11]

CHAMPION-MG OLE STUDY LIMITATIONS: Corticosteroid use was not a prespecified endpoint. Results or clinical outcomes should be interpreted with caution since the study was designed to evaluate safety and lacked a control group. The study was not designed to assess corticosteroid use or outcomes.

CS, corticosteroid; OLE, open-label extension.

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
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.

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.

Post hoc analysis:
Changes in corticosteroid use in the OLE[11]

Proportion of patients receiving steroids during the OLE[11,a]

	Day 1 (n=112)	Month 24 (n=45)	Last assessment (n=112)
Patients taking **≤10 mg** steroids/day	**41%** (46/112)	**67%** (30/45)	**63%** (71/112)
Patients taking **≤5 mg** steroids/day	**9%** (10/112)	**36%** (16/45)	**31%** (35/112)
Patients taking **0 mg** steroids/day	**1%** (1/112)	**9%** (4/45)	**12%** (13/112)

[a]Of those who were receiving corticosteroids at OLE start.[11]

Mean (SD) daily dose of corticosteroids[11]:

- First reported dosage: 17.5 (11.9) mg/day
- Last reported dosage: 11.7 (10.9) mg/day

OLE, open-label extension; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)

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.

REAL-WORLD PATIENTS: ULTOMIRIS® has been a trusted choice for patients with gMG since 2022

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

Jesse, started ULTOMIRIS in 2023

Mike, started ULTOMIRIS in 2022

Consider prescribing ULTOMIRIS for your adult patients with gMG who may be concerned about their corticosteroid use

gMG, generalized myasthenia gravis.

1. ULTOMIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc. **2.** Harris L, et al. *BMC Neurol*. 2022;22(1):172. **3.** Silvestri NJ, et al. Poster presented at: 2024 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference; March 3-6, 2024; Orlando, FL. **4.** Blackowicz, M, et al. Poster presented at: 2024 American Association of Neuromuscular & Electrodiagnostic Medicine Annual Meeting, October 15-18, 2024; Savannah, GA. **5.** Gilhus NE, et al. *Nat Rev Dis Primers*. 2019;5(1):30. **6.** Johnson S, et al. *Med Sci Monit*. 2021;27:e933296. **7.** Sanders DB, et al. *Neurology*. 2016;87(4):419-425. **8.** Murai H, et al. *Clin Exp Neuroimmunol*. 2023;14:19-27. **9.** Vu T, et al. *NEJM Evid*. 2022;1(5):1-12. **10.** Data on file. Alexion Pharmaceuticals, Inc. **11.** Vu TH, et al. *Eur J Neurol*. 2025;32(4):e70158. **12.** Myasthenia Gravis Foundation of America. Accessed June 2, 2025. https://myasthenia.org/Portals/0/ADL.pdf **13.** Vu T, et al. Presented at: 2024 American Academy of Neurology Annual Meeting, April 13-15, 2024; Denver, CO.

ALEXION® AstraZeneca Rare Disease

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

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.

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.

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.