POCKET DOSING GUIDE

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

1 INFUSION

LESS THAN 1 HOUR

ONCE EVERY 8 WEEKS[1]

Each infusion typically lasts less than 1 hour for the majority of patients.[1]

ULTOMIRIS® gives adult patients predictable, once-every-8-week maintenance dosing, starting 2 weeks after a loading dose[1]

6-7 maintenance infusions per year

- If an adverse reaction occurs during the intravenous administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician[1]
- Patients are monitored for at least 1 hour after infusions for signs or symptoms of an infusion-related reaction[1]
- The dosing schedule is allowed to occasionally vary within 7 days of the scheduled infusion day (except for the first maintenance dose of ULTOMIRIS), but subsequent doses should be administered according to the original schedule[1]
- If a patient misses an ULTOMIRIS dose, they should contact their healthcare provider immediately[1]
- ULTOMIRIS is also available as an at-home infusion for eligible patients

INDICATIONS

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.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

ULTOMIRIS is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) 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 on pages 10 and 11 and see accompanying full Prescribing Information, scan the QR code on the back page, or visit www.ultomirishcp.com/pi for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Recommended dosing regimen for adult patients with anti-AChR antibody-positive gMG or anti-AQP4 antibody-positive NMOSD[1]

ULTOMIRIS® is administered once every 8 weeks in adults, beginning 2 weeks after the loading dose.

Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administration of the first dose of ULTOMIRIS, per the current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.[1]*

- ACIP recommends that persons using complement inhibitors should be vaccinated at least 2 weeks before complement inhibitor initiation unless the risks for delaying treatment outweigh the risks for developing meningococcal disease[2]
- 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[1]
- If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible[1†]

*Follow the most current ACIP recommendations. They may differ from those provided in the the vaccine's Prescribing Information.[1]
†Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.[2]
The benefits and risks of treatment with ULTOMIRIS, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.[1]

ULTOMIRIS 100 mg/mL

The recommended weight-based dosing in adult patients with anti-AChR antibody-positive gMG or with anti-AQP4 antibody-positive NMOSD (≥40 kg [88 lb]) consists of a loading dose followed 2 weeks later by the start of maintenance dosing every 8 weeks[1]

- The dosing schedule is allowed to occasionally vary within 7 days of the scheduled infusion day (except for the first maintenance dose of ULTOMIRIS), but subsequent doses should be administered according to the original schedule
- If a patient misses an ULTOMIRIS dose, they should contact their healthcare provider immediately

AChR, acetylcholine receptor; AQP4, aquaporin-4; gMG, generalized myasthenia gravis; NMOSD, neuromyelitis optica spectrum disorder.

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Doses and infusion times for ULTOMIRIS 100 mg/mL[1]

Body Weight Range*†	Loading Dose	Maintenance Dose	Minimum Infusion Time (loading, maintenance dose)
40 kg (88 lb) to less than 60 kg (132 lb)	2400 mg	3000 mg	48 min, 54 min
60 kg (132 lb) to less than 100 kg (220 lb)	2700 mg	3300 mg	36 min, 42 min
100 kg (220 lb) or greater	3000 mg	3600 mg	24 min, 30 min

There are limits on the quantity of solutions that can be safely infused into a patient's body over a certain length of time. These quantity limits are regulated based on the body weight of a patient. Thus the rate of infusion is reduced for patients with body weight ≥40 kg to <60 kg compared to patients who weigh ≥60 kg to <100 kg.

*Body weight at time of treatment.[1]
†Approximate weight in pounds was calculated using the standard weight conversion of 1 kg=2.205 lb.
‡Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.[2]

If an adverse reaction occurs during the administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician. Monitor the patient for at least 1 hour following completion of the infusion for signs or symptoms of an infusion-related reaction.[1]

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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. 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.

ULTOMIRIS®
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300 mg/3 mL vial

ULTOMIRIS® 100 mg/mL dosing at a glance[1]

	Body Weight Range*	ULTOMIRIS Volume		Volume of 0.9% NaCl†		Total Volume (dose)	Minimum Infusion Time‡	Maximum Infusion Rate
Loading Dose Administration	40 kg (88 lb) to <60 kg (132 lb)	24 mL	+	24 mL	=	48 mL (2400 mg)	48 min	60 mL/hr
	60 kg (132 lb) to <100 kg (220 lb)	27 mL	+	27 mL	=	54 mL (2700 mg)	36 min	90 mL/hr
	100 kg (220 lb) or greater	30 mL	+	30 mL	=	60 mL (3000 mg)	24 min	150 mL/hr
Maintenance Dose Administration	40 kg (88 lb) to <60 kg (132 lb)	30 mL	+	30 mL	=	60 mL (3000 mg)	54 min	67 mL/hr
	60 kg (132 lb) to <100 kg (220 lb)	33 mL	+	33 mL	=	66 mL (3300 mg)	42 min	95 mL/hr
	100 kg (220 lb) or greater	36 mL	+	36 mL	=	72 mL (3600 mg)	30 min	144 mL/hr

*Body weight at time of treatment.[1]
†Dilute ULTOMIRIS only using 0.9% Sodium Chloride Injection, USP.[1]
‡The minimum infusion time for ULTOMIRIS 100 mg/mL maintenance doses ranges from 30 minutes to 1 hour, depending on body weight.[1]

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

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.

Please see additional Important Safety Information on pages 10 and 11 and see accompanying full Prescribing Information, scan the QR code on the back page, or visit www.ultomirishcp.com/pi for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Ordering vials of ULTOMIRIS 100 mg/mL[1]

The ULTOMIRIS 100 mg/mL formulation comes in single-dose vials with 2 volume options—1100 mg/11 mL and 300 mg/3 mL—and is a translucent, clear to yellowish colored, preservative-free solution. With ULTOMIRIS 100 mg/mL, there is an optimal vial combination (3 mL and 11 mL) for each patient weight range.

	Body Weight Range[a]	ULTOMIRIS Volume	ULTOMIRIS Vial Combinations	
			1100 mg/11 mL	300 mg/3 mL
Loading Dose Administration	40 kg (88 lb) to <60 kg (132 lb)	24 mL	–	8
	60 kg (132 lb) to <100 kg (220 lb)	27 mL	–	9
	100 kg (220 lb) or greater	30 mL	–	10
Maintenance Dose Administration	40 kg (88 lb) to <60 kg (132 lb)	30 mL	–	10
	60 kg (132 lb) to <100 kg (220 lb)	33 mL	3	–
	100 kg (220 lb) or greater	36 mL	3	1

100 mg/mL (3-mL vial)[1]:
J code, J1303;
National Drug Code, NDC 25682-025-01

100 mg/mL (11-mL vial)[1]:
J code, J1303;
National Drug Code, NDC 25682-028-01

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

Supplemental dosing of ULTOMIRIS® after PE, PP, or IVIg[1]

Concomitant use of ULTOMIRIS with PE, PP, or IVIg treatment can reduce ULTOMIRIS serum concentrations and requires a supplemental dose of ULTOMIRIS.

Body Weight Range	Most Recent ULTOMIRIS Dose	Supplemental Dose Following Each PE or PP Intervention	Supplemental Dose Following Completion of an IVIg Cycle
40 kg (88 lb) to <60 kg (132 lb)	2400 mg	1200 mg	600 mg
	3000 mg	1500 mg	
60 kg (132 lb) to <100 kg (220 lb)	2700 mg	1500 mg	600 mg
	3300 mg	1800 mg	
100 kg (220 lb) or greater	3000 mg	1500 mg	600 mg
	3600 mg	1800 mg	
Timing of ULTOMIRIS supplemental dose		Within 4 hours following each PE or PP intervention	Within 4 hours following completion of an IVIg cycle

IVIg, intravenous immunoglobulin; PE, plasma exchange; PP, plasmapheresis.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

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.

Please see additional Important Safety Information on pages 10 and 11 and see accompanying full Prescribing Information, scan the QR code on the back page, or visit www.ultomirishcp.com/pi for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Administration of ULTOMIRIS for adult patients transitioning from eculizumab[1]

- Administer the loading dose of ULTOMIRIS at the time of the next scheduled eculizumab dose
- Administer ULTOMIRIS maintenance doses once every 8 weeks, starting 2 weeks after the loading dose
- ULTOMIRIS dosing is based on body weight; see the dosing chart on page 3
- REMS enrollment is required in order to prescribe ULTOMIRIS

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.

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.

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

Preparing and administering ULTOMIRIS®[1]

1. Weigh your patient

2. Determine **how many ULTOMIRIS vials are needed based on patient weight and prescribed dose** (see pages 2-7 for reference)
   - Vials should be stored under refrigeration (2°C-8°C, 36°F-46°F) in the original carton to protect from light. Do not freeze. Do not shake
   - Each vial of ULTOMIRIS is intended for single dose only

3. Allow ULTOMIRIS vials to **come to room temperature** (18°C-25°C, 64°F-77°F) naturally, without using any heat source

4. Visually inspect each ULTOMIRIS vial to be sure there is no particulate matter or precipitation (if either is present, do not use)

5. Using aseptic technique, **withdraw the volume of ULTOMIRIS (corresponding to the prescribed dose) from the appropriate number of vials and dilute in an infusion bag using 0.9% Sodium Chloride Injection, USP** (see pages 2-7 for reference)
   - ULTOMIRIS is supplied in single-dose vials (1100 mg/11 mL and 300 mg/3 mL) to enable an optimal vial combination for each weight cohort
   - ULTOMIRIS requires dilution to a final concentration of 50 mg/mL for the 3-mL and 11-mL vials

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

ADVERSE REACTIONS

Adverse Reactions for gMG

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.

Adverse Reactions for NMOSD

Most common adverse reactions in adult patients with NMOSD (incidence ≥10%) were COVID-19, headache, back pain, arthralgia, and urinary tract infection. Serious adverse reactions were reported in 8 (13.8%) patients with NMOSD receiving ULTOMIRIS.

Please see additional Important Safety Information on pages 10 and 11 and see accompanying full Prescribing Information, scan the QR code on the back page, or visit www.ultomirishcp.com/pi for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Preparing and administering ULTOMIRIS[1] (cont'd)

6. **Gently mix** the solution (do not shake or introduce air bubbles)

7. Administer the solution immediately to your patient through a **0.2- or 0.22-micron filter**
   - If the solution is not administered immediately, the solution can be stored under refrigeration (2°C-8°C, 36°F-46°F) for ≤24 hours, taking into account the expected infusion time. Do not freeze the solution
   - When administering stored (refrigerated) solution, be sure to bring it to room temperature naturally before administering, and administer within 4 hours
   - After administration of ULTOMIRIS, flush the entire line with 0.9% Sodium Chloride Injection, USP

8. The **length of infusion time will vary** based on the dose as determined by the patient's weight, but the rate of infusion should not exceed the maximum for each dose (see page 4 for reference)

9. **Monitor your patient for at least 1 hour following infusion** to ensure no signs or symptoms of an infusion-related reaction occur
   - If an adverse reaction occurs during the administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician. Interrupt ULTOMIRIS infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur
   - Some signs of an infusion-related reaction include: lower back pain, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, bad taste, or drowsiness

USP, United States Pharmacopeia.

SELECT IMPORTANT SAFETY INFORMATION

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 full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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

INDICATIONS & IMPORTANT SAFETY INFORMATION

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INDICATIONS

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.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

ULTOMIRIS is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

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)*].

CONTRAINDICATIONS

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

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. 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.

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.

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WARNINGS AND PRECAUTIONS (continued)

ULTOMIRIS and SOLIRIS REMS (continued)

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.

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Infusion-Related Reactions

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ADVERSE REACTIONS

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Adverse Reactions for gMG

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Adverse Reactions for NMOSD

Most common adverse reactions in adult patients with NMOSD (incidence ≥10%) were COVID-19, headache, back pain, arthralgia, and urinary tract infection. Serious adverse reactions were reported in 8 (13.8%) patients with NMOSD receiving ULTOMIRIS.

DRUG INTERACTIONS

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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

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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 accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

REFERENCES: 1. ULTOMIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc. **2.** Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep.* 2020;69(9):1-41.

ONESOURCE®
Personalized Patient Support from Alexion

OneSource™ is a comprehensive, complimentary, and personalized patient support program offered by Alexion

We can help make sense of health insurance coverage, answer questions about treatment with ULTOMIRIS®, and foster connections to community resources. With our experience and resources, we're here to help you and your patients feel supported every step of the way.

OneSource Specialists assist with:

Education

- Providing your patients with educational resources and materials related to gMG and NMOSD
- Helping to answer your patients' questions about the disease or treatment logistics
- Providing information about meningococcal vaccinations and can help your patients locate a vaccination center

Health insurance navigation

- Helping your patients understand ULTOMIRIS health insurance coverage
- Exploring alternative funding options and financial resources

Ongoing support

- Guiding patients through insurance changes or finding new treatment locations
- Helping patients navigate treatment through life events, such as getting married, starting a new job, moving, or traveling
- Working with healthcare providers and specialty pharmacies to ensure patients continue receiving their medicine as prescribed

Community connections

- Providing information to patients regarding in-person and online meetings and events
- Connecting patients with other people living with gMG or NMOSD

Contact OneSource at 1-888-765-4747 or visit alexiononesource.com

OneSource gives patients the confidence of comprehensive, personalized support throughout their treatment journey

As low as

$0 Out-of-pocket costs for eligible patients

Your eligible adult patients may pay as little as $0 in out-of-pocket costs.

Copay assistance

- The Alexion OneSource CoPay Program provides financial assistance by covering eligible patients' out-of-pocket medication and infusion costs associated with ULTOMIRIS up to $15,000 US dollars per calendar year (www.alexiononesource.com/allpay)
- This program is valid ONLY for patients with commercial insurance who have a valid prescription for a US FDA-approved indication for ULTOMIRIS
- Additional requirements apply. By participating in the Program, participants acknowledge that they understand and agree to comply with the relevant terms and conditions, available at www.alexiononesource.com/copay

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

For your adult patients with anti-AChR antibody-positive gMG or for your adult patients with anti-AQP4 antibody-positive NMOSD.[1]

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

1 INFUSION LESS THAN 1 HOUR ONCE EVERY 8 WEEKS[1]

Each infusion typically lasts less than 1 hour for the majority of patients.[1]

ULTOMIRIS® gives adult patients predictable, once-every-8-week maintenance dosing, starting 2 weeks after a loading dose[1]

6–7 maintenance infusions per year

- If an adverse reaction occurs during the intravenous administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician[1]
- Patients are monitored for at least 1 hour after infusions for signs or symptoms of an infusion-related reaction[1]
- The dosing schedule is allowed to occasionally vary within 7 days of the scheduled infusion day (except for the first maintenance dose of ULTOMIRIS), but subsequent doses should be administered according to the original schedule[1]
- If a patient misses an ULTOMIRIS dose, they should contact their healthcare provider immediately[1]
- ULTOMIRIS is also available as an at-home infusion for eligible patients

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 Important Safety Information on pages 10 and 11 and see accompanying full Prescribing Information, scan this QR code, or visit www.ultomirishcp.com/pi for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Scan QR code or visit this link www.ultomirishcp.com/pi

ALEXION AstraZeneca Rare Disease