

ULTOMIRIS[®] (ravulizumab-cwvz) Initiation Guide

ULTOMIRIS is FDA approved to treat adult patients with anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) or anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD)

INDICATIONS & IMPORTANT SAFETY INFORMATION

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

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.

Please see additional Important Safety Information throughout and see 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.







ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Meningococcal Vaccinations

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 disease²
- 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 information¹

Vaccine	Primary Vaccination	Booster Vaccination
MenACWY (Menveo®, MenQuadfi®) ^{3,4}	 2 doses at least 8 weeks apart	 1 dose every 5 years, if risk remains
+		
MenB-4C (Bexsero®) ^{3,4}	 2 doses at least 1 month apart†	 1 dose 1 year following completion of primary series, and every 2 to 3 years thereafter, if risk remains
OR		
MenB-FHbp (Trumenba®) ^{3,4}	 3 doses 0, 1-2, and 6 months apart†	 1 dose 1 year following completion of primary series, and every 2 to 3 years thereafter, if risk remains

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.^{1,2‡}

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

- If your patient received meningococcal vaccines in the past, they might need additional vaccination before starting ULTOMIRIS³
- The choice of vaccine deemed medically appropriate is your independent decision
- In most cases, your patients can receive meningococcal vaccines at a physician's office or retail pharmacy
- MenACWY and MenB vaccines may be administered during the same visit but at different injection sites⁴
- To help reduce the risk of meningococcal infections, the complete series for the MenACWY and MenB vaccines should be administered³

*Follow the most current ACIP recommendations. They may differ from those provided in the vaccine's Prescribing Information.¹

†MenB vaccines are not interchangeable. Patients must receive the same product for all doses. For MenB-FHbp, if dose 2 was administered at least 6 months after dose 1, dose 3 is not needed; if dose 3 is administered earlier than 4 months after dose 2, a fourth dose should be administered at least 4 months after dose 3.³

‡Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.²

Menveo and Bexsero are registered trademarks of the GlaxoSmithKline group of companies. MenQuadfi is a registered trademark of Sanofi Pasteur Inc. Trumenba is a registered trademark of Pfizer, Inc.

Please see additional Important Safety Information throughout and see 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.

Continued on
next page 

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

ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Monitoring Patients¹

Vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of meningococcal infections and evaluate patients immediately if infection is suspected. Inform patients of the signs, symptoms, and steps to be taken for seeking immediate medical care. Meningococcal infections 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.

Signs and symptoms of meningococcal infections can include:

- fever
- fever and a rash
- headache with nausea or vomiting
- fever with high heart rate
- headache and a fever
- headache with a stiff neck or stiff back
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light



Evaluate patients immediately if an infection is suspected.

Inform patients that they will be given an ULTOMIRIS Patient Safety Card that they should carry with them at all times during and for 8 months following treatment with ULTOMIRIS. This card describes symptoms which, if experienced, should prompt the patient to seek immediate medical evaluation.

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.

See additional information on monitoring patients for infusion-related reactions on page 4.

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*.

Please see additional Important Safety Information throughout and see 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.

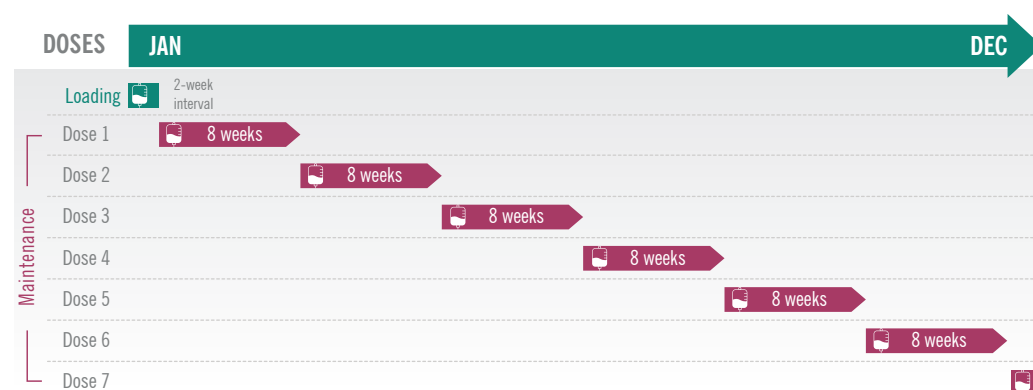
ULTOMIRIS[®]
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

ULTOMIRIS[®] (ravulizumab-cwvz)

Initiation Guide

Recommended Dosing Regimen¹

For adult patients with anti-AChR antibody-positive gMG or anti-AQP4 antibody-positive NMOSD, ULTOMIRIS treatment begins with a loading dose, followed by maintenance dosing.



The recommended dosing regimen for adult patients with gMG or NMOSD (≥ 40 kg) is based on the patient's body weight, with maintenance doses administered every 8 weeks, starting 2 weeks after the loading dose.¹

Ensure patients understand that they should adhere to the recommended dosing regimen consistently, unless otherwise advised by you.

Indications	Body weight range	Loading dose (mg)	Maintenance dose (mg) and dosing interval
gMG & NMOSD	40 kg (88 lb) to <60 kg (132 lb)	2,400	Every 8 weeks
	60 kg (132 lb) to <100 kg (220 lb)	2,700	
	≥ 100 kg (220 lb)	3,000	

Monitoring for adverse reactions during and immediately after ULTOMIRIS administration

If an adverse reaction occurs during administration of ULTOMIRIS:

- The infusion may be slowed or stopped at the physician's discretion
- Patients need to be monitored during the infusion and for ≥ 1 hour following completion of the infusion for signs or symptoms of an infusion-related reaction
- Interrupt ULTOMIRIS infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur

SELECT IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and see 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.

Continued on
next page

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

ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Recommended Dosing Regimen¹ (cont'd)

Supplemental dosing

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.

Supplemental dosing of ULTOMIRIS after PE, PP, or IVIg

Body weight range	Most recent ULTOMIRIS dose (mg)	Supplemental dose (mg) following each PE or PP intervention	Supplemental dose (mg) following completion of an IVIg cycle
40 kg (88 lb) to <60 kg (132 lb)	2,400	1,200	600
	3,000	1,500	
60 kg (132 lb) to <100 kg (220 lb)	2,700	1,500	600
	3,300	1,800	
≥100 kg (220 lb)	3,000	1,500	600
	3,600	1,800	
Timing of ULTOMIRIS supplemental dose		Within 4 hours following each PE or PP intervention	Within 4 hours following completion of an IVIg cycle

Dose reference table for ULTOMIRIS 100 mg/mL (3 mL and 11 mL Vials)

Body weight range	Dose (mg)	ULTOMIRIS volume (mL)	+	NaCl diluent volume (mL)	=	Final volume (mL)	Minimum infusion time (min)	Maximum infusion rate (mL/hr)	
Loading dose									
40 kg (88 lb) to <60 kg (132 lb)	2,400	24	+	24	=	48	48.0	60	
	60 kg (132 lb) to <100 kg (220 lb)	2,700	27	+	27	=	54	36.0	90
		3,000	30	+	30	=	60	24.0	150
Maintenance dose									
40 kg (88 lb) to <60 kg (132 lb)	3,000	30	+	30	=	60	54.0	67	
	60 kg (132 lb) to <100 kg (220 lb)	3,300	33	+	33	=	66	42.0	95
		3,600	36	+	36	=	72	30.0	144
Supplemental dose									
40 kg (88 lb) to <60 kg (132 lb)	600	6	+	6	=	12	15.0	48	
	1,200	12	+	12	=	24	25.2	57	
	1,500	15	+	15	=	30	30.0	60	
60 kg (132 lb) to <100 kg (220 lb)	600	6	+	6	=	12	12.0	60	
	1,500	15	+	15	=	30	21.6	83	
	1,800	18	+	18	=	36	25.2	86	
≥100 kg (220 lb)	600	6	+	6	=	12	10.2	71	
	1,500	15	+	15	=	30	15.0	120	
	1,800	18	+	18	=	36	16.8	129	

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.

Please see additional Important Safety Information throughout and see 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.



ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Administration¹

It is important to carefully adhere to the following preparation and administration instructions for ULTOMIRIS.

Vaccinate patients against meningococcal infection (serogroups A, C, W, Y and B) according to current ACIP recommendations at least 2 weeks prior to initiation of ULTOMIRIS.

See [Warnings and Precautions](#) for additional guidance on the management of the risk of meningococcal infection.

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 these vaccines as soon as possible.^{1,2}

Each vial of ULTOMIRIS is intended for a single dose only.

Use aseptic technique to prepare ULTOMIRIS as follows:

- STEP **1** **Calculate the number of vials needed**
Determine the number of vials to be diluted based on the individual patient's weight and the prescribed dose
-
- STEP **2** **Prior to dilution, visually inspect the solution in the vials**
The solution should be free of any particulate matter or precipitation.
Do not use if there is evidence of particulate matter or precipitation



SELECT IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (continued) ULTOMIRIS and SOLIRIS REMS (continued)

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.

Please see additional Important Safety Information throughout and see 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.

Continued on
next page 

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

ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Administration¹ (cont'd)

STEP

3

Dilute in an infusion bag

Withdraw the calculated volume of ULTOMIRIS from the appropriate number of vials and dilute in an infusion bag using 0.9% Sodium Chloride Injection, USP to a final concentration of:

- 50 mg/mL for the 3 mL and 11 mL vial sizes
- 5 mg/mL for the 30 mL vial size



Mix and administer

- Gently mix the ULTOMIRIS infusion solution after dilution. Do not shake. Protect from light. Do not freeze
- Prior to administration, allow the admixture to adjust to room temperature (18° C-25° C [64° F-77° F])
 - Do not heat the admixture in a microwave or with any heat source other than ambient air temperature
 - Inspect visually for particulate matter and discoloration prior to administration
- Administer the diluted solution immediately following preparation. Infusion must be administered through a 0.2 or 0.22 micron filter
- If the diluted ULTOMIRIS infusion solution is not used immediately, storage under refrigeration at 2° C-8° C (36° F-46° F) must not exceed 24 hours, taking into account the expected infusion time
 - Once removed from refrigeration, administer the diluted ULTOMIRIS solution within 6 hours if prepared with ULTOMIRIS 30 mL vials or within 4 hours if prepared with ULTOMIRIS 3 mL or 11 mL vials
- After administration of ULTOMIRIS, flush the entire line with 0.9% Sodium Chloride Injection, USP

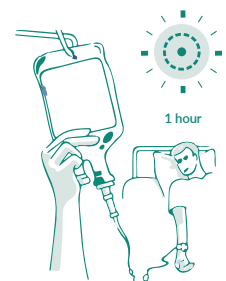


STEP

4

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.



Please see additional Important Safety Information throughout and see 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.

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

ULTOMIRIS[®] (ravulizumab-cwvz)

Initiation Guide

Enroll in ULTOMIRIS and SOLIRIS REMS

Due to the risk of meningococcal infections, prescribers must enroll in our ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS) program to obtain ULTOMIRIS.¹ Call Customer Operations at 1-888-765-4747 or visit UltSolREMS.com to learn more and enroll.¹

You must be specifically certified to prescribe ULTOMIRIS. Certification consists of review of REMS educational materials and enrollment in the ULTOMIRIS and SOLIRIS REMS program.

- STEP **1** **Review the ULTOMIRIS and SOLIRIS REMS HCP educational materials**
- Prescribing Information
 - Patient Safety Brochure
 - Prescriber Safety Brochure
 - ULTOMIRIS Patient Safety Card

- STEP **2** **Enroll in the ULTOMIRIS and SOLIRIS REMS program**
- Complete the ULTOMIRIS and SOLIRIS REMS Prescriber Enrollment online OR print and sign the Prescriber Enrollment Form.
- Mail the form to ULTOMIRIS and SOLIRIS REMS, Alexion Pharmaceuticals, Inc. ATTN: REMS Program, 121 Seaport Blvd, Boston, MA 02210
 - Fax the form to ULTOMIRIS and SOLIRIS REMS at 1-866-750-0481
 - Scan and email the form to UltSol@AlexionREMS.com

Call **1-888-765-4747** or visit www.UltSolREMS.com for more information.

SELECT IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (continued)

Other Infections (continued)

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.

Please see additional Important Safety Information throughout and see 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.

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

ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

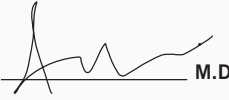
How to Write a Prescription

Treatment begins with a loading dose, followed by maintenance dosing.¹

Rx SAMPLE

Ultomiris 2400 mg IV infusion

Loading dose to be followed by
maintenance dose 2 weeks later

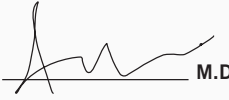


M.D.

Rx SAMPLE

Ultomiris 3000 mg IV infusion

Maintenance dose to Q8 weeks



M.D.

These **sample** prescriptions indicate the loading dose and maintenance dose for ULTOMIRIS in a patient weighing 40 kg (88 lb).¹

Administer ULTOMIRIS at the recommended dosage regimen time points. The dosing schedule can occasionally vary within 7 days of the scheduled infusion day—except for the first maintenance dose of ULTOMIRIS.¹

Treatment sites

ULTOMIRIS is a treatment that is given by IV infusion.¹ Depending on the patient's insurance and location, infusions can be administered at:



A prescriber's office



An infusion center



A patient's home

An Alexion OneSource™ representative can assist your patients with locating an infusion center.

SELECT IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (continued)

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

Intravenous administration 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 treated with ULTOMIRIS. These events included lower back pain, drop 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.

Please see additional Important Safety Information throughout and see 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.



ULTOMIRIS[®] (ravulizumab-cwvz)

Initiation Guide

Ordering and Storing

Place your order with an authorized specialty distributor OR send your completed prescription to the payer-designated specialty pharmacy.

An Alexion Customer Operations Representative will work with either party to facilitate order processing and delivery.

Storage and handling¹

- Store ULTOMIRIS vials in their original cartons, refrigerated at 2° C-8° C (36° F-46° F), to protect from light until time of use
- If the diluted ULTOMIRIS infusion solution is not used immediately, storage under refrigeration at 2° C-8° C (36° F-46° F) must not exceed 24 hours, taking into account the expected infusion time. Once removed from refrigeration, administer the diluted ULTOMIRIS infusion solution within 6 hours if prepared with ULTOMIRIS 30 mL vials or within 4 hours if prepared with ULTOMIRIS 3 mL or 11 mL vials
- **DO NOT FREEZE; DO NOT SHAKE**

Ordering ULTOMIRIS¹

Single-dose vials, one vial per carton

NDC 25682-025-01 SINGLE-UNIT, 300 mg/3 mL (100 mg/mL)

NDC 25682-028-01 SINGLE-UNIT, 1,100 mg/11 mL (100 mg/mL)



SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

Adverse Reactions for gMG

Most common adverse reactions in adult patients with gMG (incidence $\geq 10\%$) 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 $\geq 10\%$) 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

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 additional Important Safety Information throughout and see 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.

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

ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Begin With OneSource™

Connect patients to OneSource for ongoing support.

OneSource is a comprehensive, complimentary, personalized patient support program offered by Alexion available for eligible enrolled adult patients with anti-AChR antibody-positive gMG or anti-AQP4 antibody-positive NMOSD. Our team is specially trained in rare diseases, and each person plays a unique role in helping to support your patients' needs. OneSource offers assistance with:



EDUCATION

- Providing your patients with educational resources and materials related to anti-AQP4 antibody-positive NMOSD
- Helping to answer your patients' questions about the disease or treatment logistics
- How my patient can apply for the program
- Providing information about meningococcal vaccinations and can help your patients locate a vaccination center



ONGOING SUPPORT

- Guiding patients through insurance changes or finding new treatment locations
- Have patients review and sign the completed form, then fax the completed form to OneSource at 1-800-420-5150 or email to onesource@alexion.com
- 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



HEALTH INSURANCE NAVIGATION

- Helping patients understand their health insurance coverage for ULTOMIRIS
- Exploring alternative funding options and financial resource



COMMUNITY CONNECTIONS

- Providing information about in-person and online meetings and events
- Connecting patients with other people living with anti-AQP4 antibody-positive NMOSD

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

SELECT IMPORTANT SAFETY INFORMATION

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 see 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.

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

ULTOMIRIS® (ravulizumab-cwvz)

Initiation Guide

Alexion OneSource™ CoPay Program

The Alexion OneSource CoPay Program helps patients pay for eligible out-of-pocket medication and infusion costs. For more information, please visit www.alexiononesource.com/copay.

To be eligible for this program, your patient must:

- ✓ Be signed up for patient services through OneSource
- ✓ Be prescribed ULTOMIRIS for an FDA-approved indication
- ✓ Have commercial insurance
- ✓ Reside in the United States or its territories

How my patient can apply for the program



Fill out the Alexion Patient Start Form

The enrollment form can be found at alexiononesource.com



Submit form to OneSource

Have patients review and sign the completed form, then fax the completed form to OneSource at 1-800-420-5150 or email to onesource@alexion.com



Receive CoPay ID number from OneSource

Patients will receive communication from OneSource containing the CoPay ID number



Provide CoPay ID number to site of care

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

IMPORTANT NOTICE: The Alexion OneSource™ CoPay Program ("Program") pays for eligible out-of-pocket medication and infusion costs, where applicable, associated with ULTOMIRIS up to \$15,000 US dollars per calendar year. The Program is not valid for beneficiaries or recipients of any federal, state, or government-funded healthcare program, including Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense or TRICARE, or other federal or state programs (including any state prescription drug assistance programs). No claim for reimbursement of any out-of-pocket expense amount covered by the Program may be submitted to any third-party payer, whether public or private. This Program cannot be combined with any other rebate, coupon, free trial, or similar offer. Patients residing in Massachusetts or Rhode Island are eligible for assistance with medication costs but are not eligible for assistance with infusion costs. Alexion reserves the right to rescind, revoke, or amend the Program without notice. By participating in the Program, participants acknowledge that they understand and agree to comply with the complete terms and conditions, available at alexiononesource.com/copay.

Please see additional Important Safety Information throughout and see 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

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. 3. Centers for Disease Control and Prevention. ACIP adult immunization schedule. Updated February 29, 2024. Accessed March 20, 2024. <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf> 4. Centers for Disease Control and Prevention. Meningococcal vaccination: what everyone should know. Updated November 20, 2023. Accessed March 20, 2024.