For your adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive or your adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive[1]

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

Meningococcal vaccination guide and FAQs

How to vaccinate patients starting ULTOMIRIS®

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.

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

When initiating ULTOMIRIS® treatment, help protect your patients with gMG or NMOSD against meningococcal infections[1,2]

We understand the importance of patient safety. That is why we are providing this resource to help you.

Spend less time navigating meningococcal vaccination—and more time caring for your patients

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.

About meningococcal infections

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

People receiving complement inhibitors are at an increased risk for meningococcal infections.[2]

Why are people receiving complement inhibitors such as ULTOMIRIS more susceptible to meningococcal infections?

- Encapsulated *N. meningitidis* causes meningococcal infections[3,4]
- The complement system protects the body against this encapsulated bacteria[5]

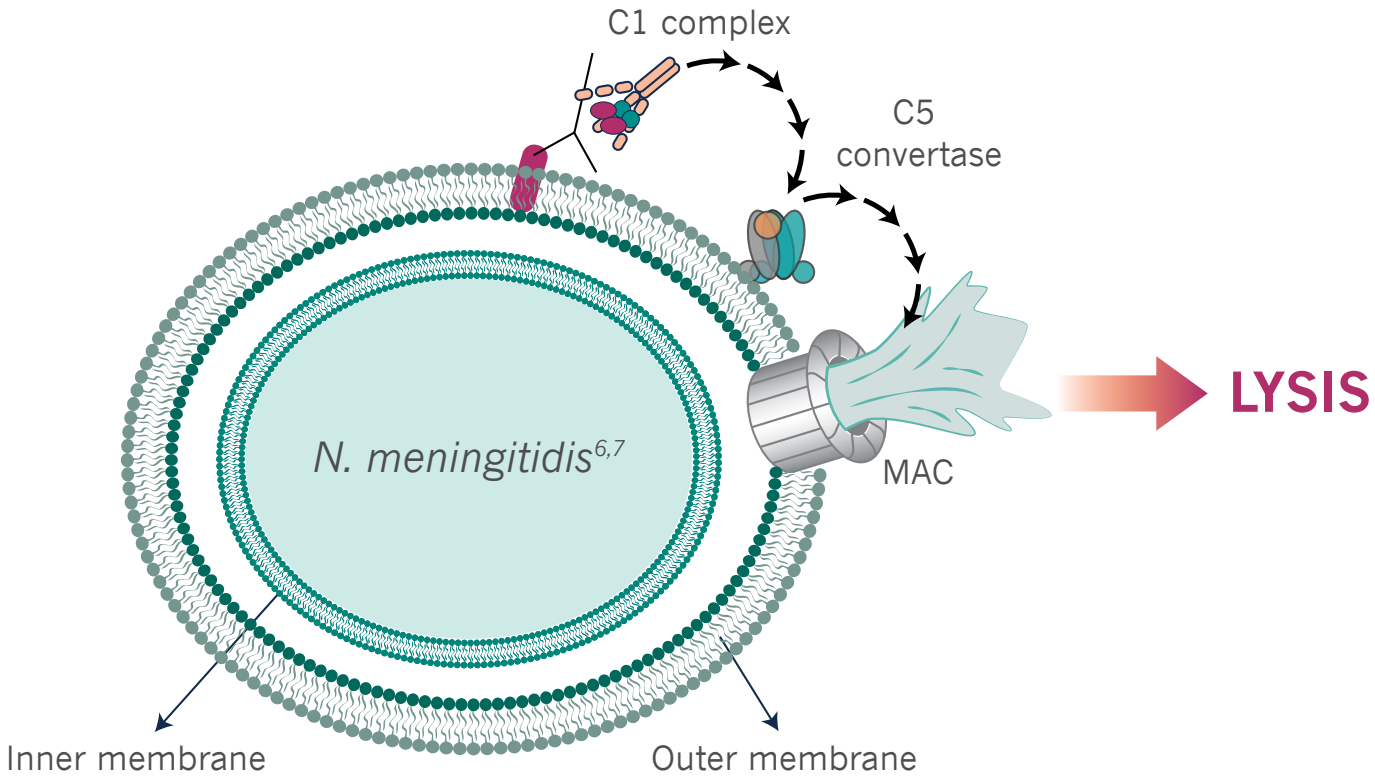


Image adapted from Doorduijn DJ, et al. *Bioessays.* 2019;41(10):e1900074 and Schneider MC, et al. *Trends Microbiol.* 2007;15(5):233-240.

People receiving complement inhibitors such as ULTOMIRIS are less able to rely on the complement system to defend against *N. meningitidis*, making them more susceptible to meningococcal infections[5,8,9]

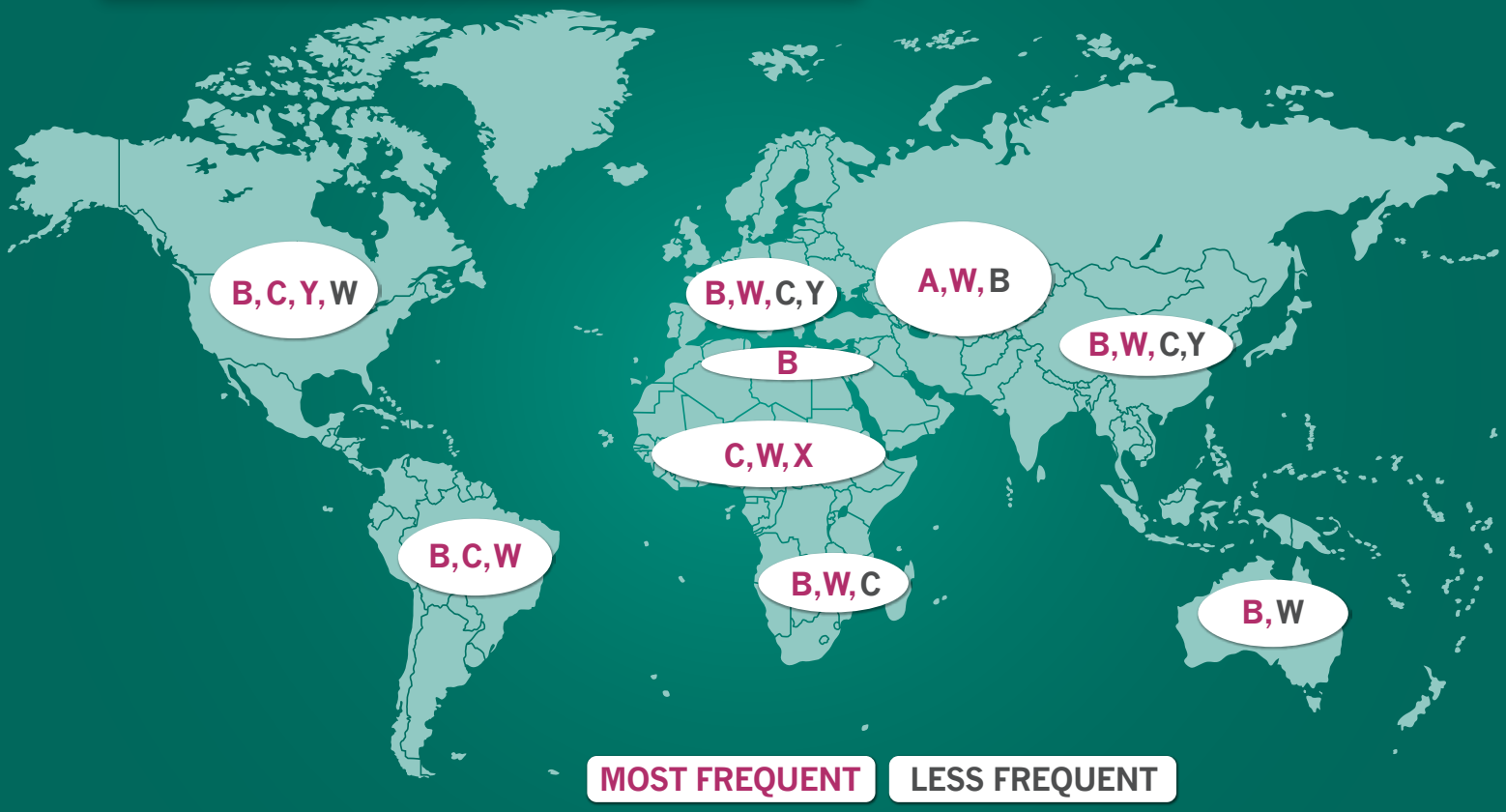
MAC, membrane attack complex.

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

Specific *N. meningitidis* serogroups cause meningococcal infection[3]

There are at least 13 types of *N. meningitidis* serogroups. A, B, C, W, X, and Y cause most meningococcal infections.[3]

Serogroup geographic distribution, 2019[10]



Meningococcal vaccinations against these specific serogroups help reduce the risk of meningococcal infections[4,11]

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*.

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

Help protect your patients starting ULTOMIRIS®[1]

Several meningococcal vaccines are available in the United States[2,8,12,13]

Trade name	Serogroups included	Approved ages
Menveo®	A, C, W, Y	2 months–55 years*
MenQuadfi®	A, C, W, Y	2 years and older
Trumenba®	B	10–25 years†
Bexsero®	B	10–25 years†

*According to ACIP guidelines, vaccine may be administered to patients older than 55 years of age.[2,8,12]
†According to ACIP guidelines, vaccine may be administered to patients older than 25 years of age.[2,8,12]

FAQs

Do ACIP recommendations provide information regarding meningococcal vaccination for a variety of patient age groups?

According to ACIP recommendations, meningococcal vaccines should be administered to patients starting complement inhibitors, regardless of their age.[8,12]

Writing a vaccination prescription and letter of medical necessity may improve vaccine access and insurance coverage.

Sample letter of medical necessity

Are meningococcal vaccinations covered by health insurance?

Meningococcal vaccinations are recommended by ACIP and are typically covered by health insurance. Medicare Part D patients are covered at no out-of-pocket cost.[9,14,15]

Contact a OneSource™ Patient Navigator or Patient Liaison at 1-888-765-4747 for a benefits investigation for your patient.

Contact your Field Reimbursement Manager for coding and billing questions. You may be able to bill for the vaccination under a treatment plan for medical coverage.

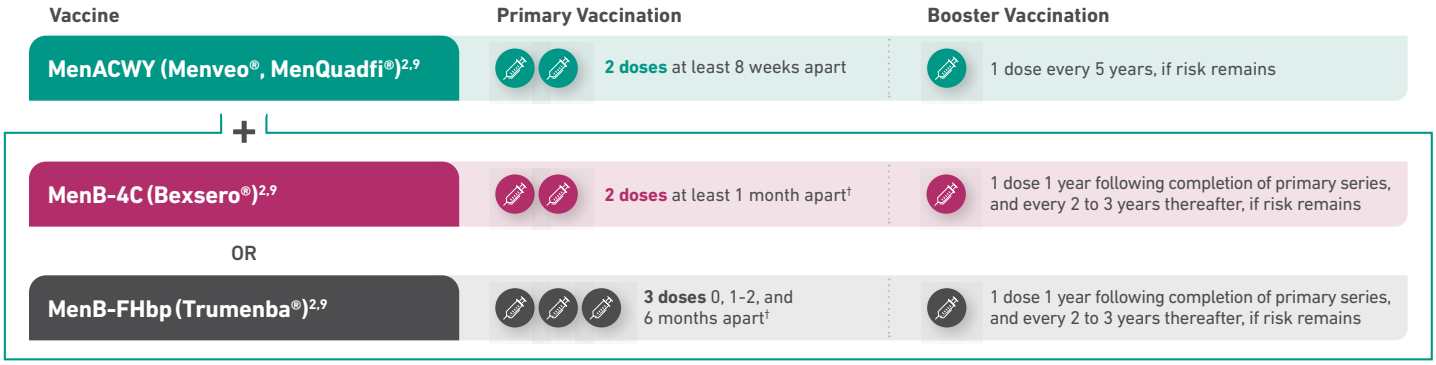
ACIP, Advisory Committee on Immunization Practices.

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

Meningococcal vaccination protocol for patients starting ULTOMIRIS®

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 patients 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[8]
- 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.[1,8‡]

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]

Vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.[1]

- If your patient received meningococcal vaccines in the past, they might need additional vaccination before starting ULTOMIRIS[1,9]
- 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 sites[16]
- To help reduce the risk of meningococcal infections, the complete series for the MenACWY and MenB vaccines should be administered[9]

ULTOMIRIS is available only through a Risk Evaluation and Mitigation Strategy (REMS) program

- You must enroll and complete certification in the ULTOMIRIS and SOLIRIS REMS program before you can prescribe ULTOMIRIS[1]
- Visit **UltSolREMS.com** to enroll in the ULTOMIRIS and SOLIRIS REMS program or call 1-888-765-4747

*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.[9]
‡Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.[8]

Please see the respective meningococcal vaccine Prescribing Information for complete details, including vaccine Warnings, Precautions, and Contraindications.

FAQs

Must patients receive the same brand of vaccine for both the primary series and the boosters?

MenACWY vaccines are interchangeable for patients 2 years of age and older.[8,12]

MenB vaccines are not interchangeable. Patients must receive the same product for all doses.[9]

Which prophylactic antibiotics can be prescribed?

Several antibiotics are available for the treatment of meningococcal infections, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.[8]

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]

When should patients transitioning to ULTOMIRIS from an immunosuppressive therapy be vaccinated?

When patients transition from an immunosuppressive therapy, vaccines might be less effective due to a period of altered immunocompetence. Assess the degree of immunocompetence to determine whether vaccination should be delayed.[17]

What is required for patients who were vaccinated before starting a complement inhibitor and who are transitioning to ULTOMIRIS?

These patients do not need to be revaccinated as long as their meningococcal vaccinations are up to date. Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy.[1,8]

SELECT IMPORTANT SAFETY INFORMATION

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

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

Vaccination administration and logistics

It is important for patients receiving ULTOMIRIS® to maintain their meningococcal vaccination schedule.[1,2,8]

ONESOURCE®
Personalized Patient Support from Alexion
1-888-765-4747

OneSource™ can provide comprehensive vaccination support, including providing patients with information about meningococcal vaccinations, helping patients locate a vaccination center, and answering questions about vaccination logistics.

Find a PEM

Patient Education Managers (PEMs) can help your patients learn more about the vaccination process through educational one-on-ones as well as local educational sessions and community events.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

ULTOMIRIS and SOLIRIS REMS (continued)

(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

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.

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

FAQs

Where should patients go to get vaccinated?

You or your patients' primary care physician can recommend a vaccination location. **Patients who are enrolled in OneSource™ can also receive comprehensive vaccination support, including assistance identifying vaccination options.**

Your patients may receive meningococcal vaccinations at a/an[2]:

- **Primary care physician's office**
- **Retail pharmacy**
- **Infusion center**
- **Local health department**
- **Vaccination or community health clinic**
- **Hospital**

Can patients receive different vaccinations during the same visit?

Yes, MenACWY and MenB vaccines may be administered during the same visit, but at different injection sites. Flu and COVID-19 vaccines may also be administered during the same visit.[16,18,19]

What should I do if my patients do not remember their vaccination dates or MenB brand?

OneSource can provide this information to patients if they have previously reported it to OneSource. OneSource can also provide vaccination cards to help patients track their vaccinations.

If patients cannot find this information, they should restart the primary vaccination series.[12]

SELECT IMPORTANT SAFETY INFORMATION

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.

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.

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.
Please see accompanying full prescribing information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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

Help protect early so you can treat without delay

Make sure your patients starting ULTOMIRIS® receive their meningococcal vaccinations at least 2 weeks before beginning treatment[1,8]

Helpful resources

More information to help you and your patients manage the vaccination process

Adult Immunization Schedule: www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

ACIP Vaccine Recommendations: www.cdc.gov/vaccines/hcp/acip-recs/

ONESOURCE®
Personalized Patient Support from Alexion

Get additional vaccination support at
AlexionOneSource.com or call 1-888-765-4747

Please see accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full prescribing information for SOLIRIS, 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.** Centers for Disease Control and Prevention. Updated October 12, 2021. Accessed February 3, 2023. https://www.cdc.gov/vaccines/vpd/mening/public **3.** Rouphael NG, et al. *Methods Mol Biol.* 2012;799:1-20. **4.** Feldman C, et al. *Pneumonia (Nathan).* 2019;11:3. **5.** Uria MJ, et al. *J Exp Med*. 2008;205(6):1423-1434. **6.** Doorduijn DJ, et al. *Bioessays*. 2019;41(10):e1900074. **7.** Schneider MC, et al. *Trends Microbiol*. 2007;15(5):233-240. **8.** Mbaeyi SA, et al. *MMWR Recomm Rep.* 2020;69(9):1-41. **9.** Centers for Disease Control and Prevention. Updated February 29, 2024. Accessed March 24, 2024. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf **10.** World Health Organization. Accessed March 24, 2024. https://cdn.who.int/media/images/default-source/health-topics/meningitis/map-serogroup-distribution-2019.png?sfvrsn=af422ab2_2 **11.** van Deuren M, et al. *Clin Microbiol Rev*. 2000;13(1):144-166. **12.** Immunize.org. Updated January 19, 2024. Accessed March 24, 2024. https://www.immunize.org/catg.d/p4210.pdf **13.** MenQuadfi. Prescribing information. Sanofi Pasteur Inc. **14.** Centers for Disease Control and Prevention. Updated September 28, 2023. Accessed March 24, 2024. https://www.cdc.gov/vaccines/adults/pay-for-vaccines.html **15.** Centers for Medicare & Medicaid Services. Updated June 2023. Accessed March 24, 2024. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/vaccines-part-d-factsheet-icn908764.pdf **16.** Centers for Disease Control and Prevention. Updated October 12, 2021. Accessed March 24, 2024. https://www.cdc.gov/vaccines/vpd/mening/hcp/administering-vaccine.html **17.** Centers for Disease Control and Prevention. Updated November 20, 2023. Accessed March 24, 2024. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.pdf **18.** Alderfer J, et al. *Hum Vaccin Immunother*. 2019;15(9):2205-2216. **19.** Centers for Disease Control and Prevention. Updated January 23, 2024. Accessed March 24, 2024. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect.html#:~:text=To%20find%20COVID-19%20vaccine,-800-232-0233

ALEXION®
AstraZeneca Rare Disease