

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

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

ULTOMIRIS[®]

IS

moving forward with
proven symptom control^{*†}

Image is not of an actual patient.

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

Learn about the importance of the meningococcal vaccination
requirement before starting ULTOMIRIS

The first and only long-acting C5 inhibitor with 8 weeks of freedom
between infusions, starting 2 weeks after an initial dose

*Symptoms were assessed throughout the 26-week trial by the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, which assesses the impact of gMG on daily functions (through 8 signs and symptoms that are typically affected in gMG).

†Many patients continued taking other medications for gMG throughout the 26-week study.

ULTOMIRIS targets a part of the immune system that contributes to muscle damage in gMG and fights certain infections such as meningococcal infections. You must complete or update your meningococcal vaccines at least 2 weeks before starting ULTOMIRIS. If your healthcare provider decides that urgent treatment with ULTOMIRIS is needed, you should get the meningococcal vaccines as soon as possible. If you have not been vaccinated and ULTOMIRIS must be started immediately, you should also receive antibiotics for as long as your healthcare provider tells you. **It can take up to 6 months to receive the meningococcal vaccinations.** Starting the vaccination process early may help ensure you're ready to start ULTOMIRIS.

C5, complement component 5.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.

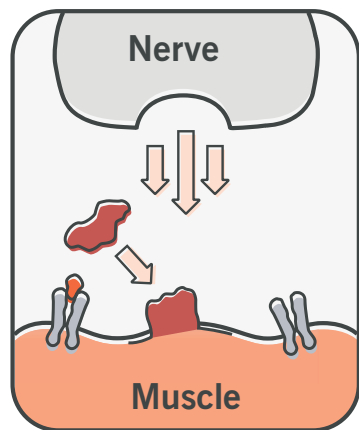
Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.

Why are meningococcal vaccinations necessary before starting ULTOMIRIS®?

C5 is a key protein that helps your body fight off infections. In anti-AChR antibody-positive gMG, muscle function is lost when a faulty immune response mistakenly attacks muscle cells; this is activated in part by C5. ULTOMIRIS blocks C5.

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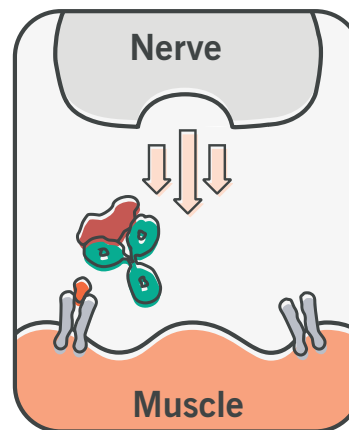
Muscle cell with gMG



C5 enables the buildup of proteins on the surface of the muscles that result in muscle cell damage. The muscle cell damage may be the cause of gMG symptoms, such as muscle weakness.

In anti-AChR antibody-positive gMG, antibodies block receptors on muscle cells from receiving movement signals from the nerves. The immune system registers the receptor blockage as a threat and mistakenly damages the muscles in response.

Muscle cell in treatment with ULTOMIRIS



ULTOMIRIS blocks C5 to prevent the buildup of those proteins.

ULTOMIRIS is the first and only long-acting C5 inhibitor—it binds to and blocks C5 immediately and completely.

Key:



Movement signals



Receptor



ULTOMIRIS



Antibody-blocked receptor



C5

The exact way ULTOMIRIS works as a treatment for gMG is unknown.

By targeting C5, ULTOMIRIS may lower the ability of your immune system to fight meningococcal infections, so it is necessary to complete or update your meningococcal vaccinations at least 2 weeks before starting treatment. Before you start ULTOMIRIS, ask your doctor about meningococcal vaccinations.

AChR, acetylcholine receptor; gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.



My neurologist told me about **ULTOMIRIS[®]**, what it could do, how it worked, the side effects to look out for, and the vaccines that I needed to have to begin the infusion.



Brittany, living with gMG, has received compensation from Alexion Pharmaceuticals, Inc.

Image is not of an actual patient.

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

gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.

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ULTOMIRIS[®] was shown to provide proven gMG symptom control, based on MG-ADL

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After the first 26 weeks of a clinical trial, people on ULTOMIRIS saw:

2[×] improvement in activities of daily living*

Such as: seeing, chewing, breathing, talking, brushing teeth, combing hair, and rising from a chair

How were these results measured?

The impact of gMG symptoms was measured using:

- the **Myasthenia Gravis Activities of Daily Living (MG-ADL)** is a scale that measures the impact of 8 gMG symptoms on daily functions. MG-ADL total scores range from 0 to 24, with higher scores indicating more severe gMG symptoms
- the **Quantitative Myasthenia Gravis (QMG) scale**, a 13-item doctor-reported symptom improvement scale that assesses muscle weakness, was also used in the ULTOMIRIS study. QMG total scores can range from 0 to 39, with higher scores indicating more severe gMG symptoms

3[×] reduction in muscle weakness[†]

Such as: eye and facial movements, swallowing, speaking, hand gripping, head lifting, and limb stretching

*Versus placebo from baseline to Week 26 of the clinical trial, according to the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale. In the study, the average baseline MG-ADL total score for the 86 people on ULTOMIRIS was 9.1; for the 89 people on placebo, it was 8.9. At Week 26, the average change in total score from baseline was -3.1 for people receiving ULTOMIRIS and -1.4 for those receiving placebo. Many people continued taking other medicines throughout the study.

†Versus placebo from baseline to Week 26 of the clinical trial, according to the Quantitative Myasthenia Gravis (QMG) scale. In the study, the average baseline QMG total score for the 86 people on ULTOMIRIS was 14.8; for the 89 people on placebo, it was 14.5. At Week 26, the average change in total score from baseline was -2.8 for people receiving ULTOMIRIS and -0.8 for those receiving placebo. Many people continued taking other medicines throughout the study.

Placebo is an inactive substance or treatment that looks the same and is given the same way as the medication being studied.

gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:** fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

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ULTOMIRIS® was studied in a 26-week clinical trial that included adults with varying degrees of severity of anti-AChR antibody-positive gMG



The CHAMPION-MG trial measured the impact of ULTOMIRIS on daily activities and muscle weakness. It included 175 people who were randomly split into 2 groups: those taking ULTOMIRIS (86 people) and those receiving placebo (89 people).

- Over 90% of people in the trial had mild or moderate gMG*
- At their first dose of ULTOMIRIS, most (90%) people were taking an immunosuppressive therapy. If people were receiving immunosuppressive therapies at the start of the study, they were required to continue taking them at stable doses throughout the initial study period of 26 weeks
- After Week 26 of the trial, all study participants were eligible to receive ULTOMIRIS for an extension period of up to 4 additional years

Side effects were studied in the ULTOMIRIS trial (CHAMPION-MG)

The following side effects were experienced by 5% or more of people in the study and at a greater frequency with ULTOMIRIS vs placebo

	ULTOMIRIS (86 people)	Placebo (89 people)
Diarrhea	15%	12%
Abdominal pain	6%	0%
Upper respiratory tract infection	14%	8%
Urinary tract infection	6%	4%
Back pain	8%	6%
Dizziness	9%	3%

- Serious side effects were reported in 20 people (23%) with gMG receiving ULTOMIRIS and in 14 people (16%) receiving placebo
- The most frequent serious side effects were infections reported in at least 8 people (9%) treated with ULTOMIRIS and in 4 people (4%) treated with placebo. Of these infections, one fatal case of COVID-19 pneumonia was identified in a person treated with ULTOMIRIS and one case of infection led to stoppage of ULTOMIRIS
- Only 2 people taking ULTOMIRIS stopped treatment due to side effects compared to 3 people taking placebo
- The most common side effects reported in $\geq 10\%$ of people taking ULTOMIRIS were diarrhea and upper respiratory tract infection

*As defined by Myasthenia Gravis Foundation of America (MGFA) clinical classification.

AChR, acetylcholine receptor; gMG, generalized myasthenia gravis.

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My neurologist explained to me that I needed to complete my meningococcal vaccinations at least 2 weeks before my first dose because ULTOMIRIS[®] is a medicine that affects your immune system and can lower the ability of your immune system to fight infections.



Jan, living with gMG, has received compensation from Alexion Pharmaceuticals, Inc.



gMG, generalized myasthenia gravis.

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

SELECT IMPORTANT SAFETY INFORMATION

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

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How does a person get a meningococcal infection?

A person can get exposed to meningococcal infection through close contact with an infected person. It can spread through saliva by:

- coughing
- sneezing
- kissing
- sharing drinks, utensils, or toothbrushes

What are the signs and symptoms of a serious meningococcal infection to watch for?

Any of the following could signal a serious meningococcal infection:

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

If you have any of these signs and symptoms, or are unsure, call your healthcare provider or get emergency medical care right away.

gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start ULTOMIRIS right away and are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING regarding serious meningococcal infections.**

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Understanding real-world data

What is real-world data?

Real-world data are collected outside of clinical trials, for example, during your regular doctor visits. This type of data can offer some insight into use, benefits, or risks of a drug in everyday settings. However, because they are collected this way, there are limitations to their use. For example, previously collected real-world data cannot be used to assess future risk. Real-world data are often measured in patient-years. Consider this data carefully when making decisions since it may not be complete.

What are patient-years?

Patient-years measure how much time people spent in a study and on a drug in the real world to help doctors better understand how often certain things happen, such as side effects.

It is calculated like this:



For example:

- If 1 patient took a medication for 1 year, that would equal 1 patient-year
- If 100 patients took a medication for 1 year, that would equal 100 patient-years
- If 100 patients took a medication for 10 years, that would equal 1000 patient-years

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**
 1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
 2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.

Real-world data observations

- ULTOMIRIS has been used and studied across 4 FDA-approved indications^{‡§}:
 - Worldwide, in over 34,000 patient-years of use over 6 years, there were 33 cases of meningococcal infection
 - For people treating their PNH or aHUS diseases, 2 fatalities were reported, representing a 0.01% mortality rate per 100 patient-years
 - In the US, in over 15,000 patient-years of use, there were 9 cases of meningococcal infection
 - There were 0 reported cases of meningococcal infection or death in people treating their gMG or NMOSD diseases

Alexion is committed to ongoing data analysis to better understand diseases like gMG.

Talk to your healthcare team about any questions you may have to better understand the real-world data.

All patients received required meningococcal vaccinations. Vaccinations do not eliminate the risk of meningococcal infections, despite the development of antibodies afterward.

These data are from the Alexion safety database. Data may be missing or incomplete as they are limited to cases reported by prescribing clinicians.

*Data collected from the Alexion safety database for ULTOMIRIS through December 31, 2023. Results or clinical outcomes should be interpreted with caution.

†Data for ULTOMIRIS across approved indications were analyzed using the MedDRA High-Level Term “*Neisseria* infection,” which included only *Neisseria meningitidis*-associated cases.

‡Including anti-acetylcholine receptor (AChR) antibody-positive gMG, anti-aquaporin-4 (AQP4) antibody-positive NMOSD, aHUS, and PNH.

§aHUS, atypical hemolytic uremic syndrome; gMG, generalized myasthenia gravis; NMOSD, neuromyelitis optica spectrum disorder; MedDRA, Medical Dictionary for Regulatory Activities; PNH, paroxysmal nocturnal hemoglobinuria.

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS (continued)

3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:** fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Get to know the meningococcal vaccination process

1

Talk to your doctor about getting vaccinated before starting ULTOMIRIS[®]. **It's necessary to complete or update your meningococcal vaccinations at least 2 weeks before starting treatment.**

If you had a meningococcal vaccine in the past, **you might need additional vaccines** before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines for meningococcal infections.

2

Once your doctor prescribes the meningococcal vaccinations, **consider calling OneSource[™]**. OneSource is a free, personalized patient support program that can help you find the vaccination site closest to you and may be able to find ways for you to cover vaccination costs.

3

After receiving your first dose of vaccines, schedule your next appointments. OneSource can also help you **keep track of your vaccination schedule** and remind you of when your next appointment is.

You can contact OneSource to find a vaccination site at **1-877-GMG-ULTO (877-464-8586)** or visit [AlexionOneSource.com](https://www.AlexionOneSource.com)

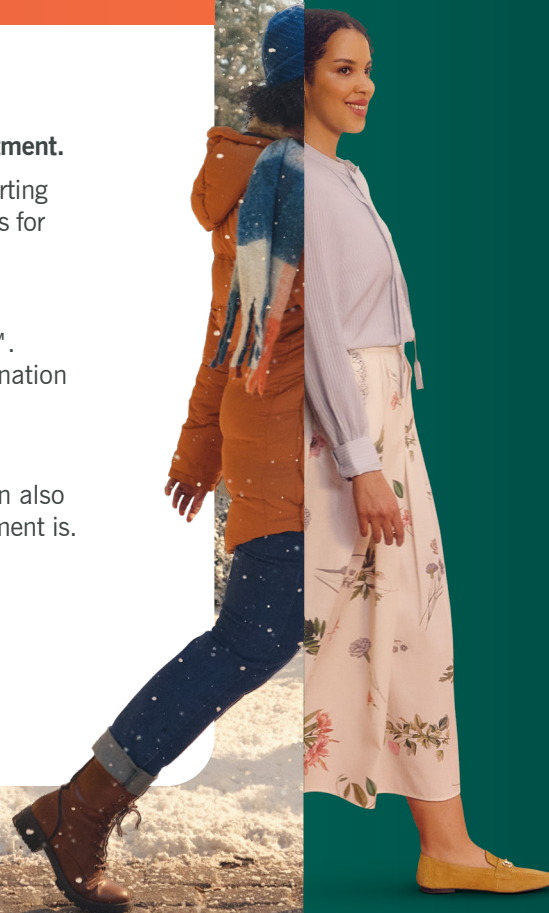


Image is not of an actual patient.

SELECT IMPORTANT SAFETY INFORMATION

ULTOMIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Certain people may be at risk of serious infections with gonorrhea.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.

Enroll in OneSource for vaccination support and other resources

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OneSource is a free and personalized patient support program from Alexion designed to support your specific needs.

A OneSource Specialist (OSS) can:



Help you find a place to get vaccinated



Give you useful tools and information about meningococcal vaccinations



Assist you in navigating your insurance plan or other resources for covering the vaccination costs



Provide you with additional resources, such as the Patient Safety Card, when you visit [alexiononesource.com/ultomiris/tools-and-resources](https://www.alexiononesource.com/ultomiris/tools-and-resources)

For vaccination support, call OneSource at 1-877-GMG-ULTO (877-464-8586)

To be eligible, you must be signed up for patient services through OneSource and be prescribed ULTOMIRIS for an FDA-approved indication. You must also be prescribed vaccinations by your healthcare provider.



Have questions about your treatment journey?

Connect with a OneSource Patient Education Manager (PEM)—a PEM can empower you with resources and offer personalized support.

Visit www.mygmgpem.com to find a PEM.

Not an actual PEM.

SELECT IMPORTANT SAFETY INFORMATION

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.

Learn more about the vaccines

Before starting ULTOMIRIS[®], you will receive a course of meningococcal vaccinations. This course will include **MenACWY** and **MenB** vaccines, and you will need to have both to complete or update your meningococcal vaccinations. Which vaccines you will need and when you will receive them will depend on your prior vaccination history and the direction of your healthcare provider.

Meningococcal vaccinations help protect against one or more serogroups of the bacteria that cause meningococcal disease. **MenACWY vaccines (Menveo[®] and MenQuadfi[®])** help protect against 4 serogroups: A, C, W, and Y. **MenB vaccines (Bexsero[®] and Trumenba[®])** help protect against serogroup B. The choice of vaccine brand deemed medically appropriate is the decision of your treating healthcare provider. You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.

These examples do not include all meningococcal vaccines. For more information, please speak to your healthcare provider about what is right for you.

Required vaccines:



The Advisory Committee on Immunization Practices (ACIP) recommends that adults at increased risk receive both types of meningococcal vaccines (MenACWY and MenB).

If you have not been vaccinated and treatment must be started right away, you should receive the required vaccine(s) as soon as possible and you should also receive antibiotics to take for as long as your healthcare provider tells you.

Booster vaccines may also be necessary:

- **MenACWY:** 1 dose every 5 years if risk remains
- **MenB:** 1 dose 1 year after completion of primary series and every 2 to 3 years if risk remains

Ask your doctor to let you know when you'll need a booster.

SELECT IMPORTANT SAFETY INFORMATION

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever
- are pregnant or plan to become pregnant. It is not known if ULTOMIRIS will harm your unborn baby.
 - **Pregnancy Registry:** There is a registry for pregnant women who take ULTOMIRIS to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ULTOMIRIS, talk to your healthcare provider about how you can join this registry or you may contact the registry at 1-833-793-0563 or www.UltomirisPregnancyStudy.com to enroll.
- are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.



Image is not of an actual patient.

See an example of the primary vaccination timeline

You can get your primary vaccinations in **just 3 or 4 appointments**.

These are example timelines. Your doctor may recommend a different schedule based on your needs.





 **MenACWY**
2 doses at least 8 weeks apart +  **MenB**
3 doses 0, 1-2, and 6 months apart


EXAMPLE 1: VACCINATE IN 3 APPOINTMENTS

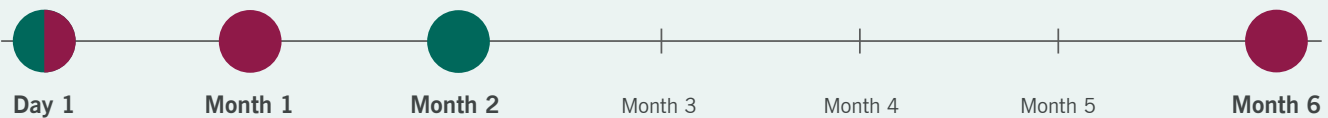


OR

 **Dose 1:**
2 injections given
at the same time

 **Dose 2:**
2 injections can be given
together or spaced apart

 **Dose 3:**
1 injection



EXAMPLE 2: VACCINATE IN 4 APPOINTMENTS

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.

What if my doctor decides I need to start ULTOMIRIS® right away?

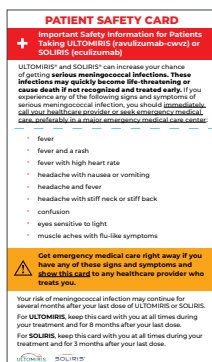
You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first infusion with ULTOMIRIS.

Your doctor may decide that the benefit of starting ULTOMIRIS right away outweighs the risk of meningococcal infections. If so, they will work with you to ensure you receive the required vaccine(s) as soon as possible and start you on antibiotics, which you should take for as long as your doctor tells you to take them.

Meningococcal vaccines do not prevent all meningococcal infections.

ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.

Carry your Patient Safety Card



Your healthcare provider will give you a Patient Safety Card with information about your risk of serious meningococcal infection.

Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS.

It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

SELECT IMPORTANT SAFETY INFORMATION

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, stomach (abdominal) pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, or bad taste. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion-related reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

The most common side effects of ULTOMIRIS in people with gMG are diarrhea and upper respiratory tract infections.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.



OneSource calls to make sure that you've got your meningococcal vaccines taken care of at least 2 weeks before you start your ULTOMIRIS[®] infusion. They also make sure that you get your booster shots taken care of. The same person contacts me every time.



Brittany, living with gMG, has received compensation from Alexion Pharmaceuticals, Inc.

gMG, generalized myasthenia gravis.

Image is not of an actual patient.

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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INDICATIONS & IMPORTANT SAFETY INFORMATION



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INDICATIONS

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat:

- adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- adults and children 1 month of age and older with a disease called atypical Hemolytic Uremic Syndrome (aHUS). ULTOMIRIS is not used in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with a disease called generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adults with a disease called Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody positive.

It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

It is not known if ULTOMIRIS is safe and effective for the treatment of gMG or NMOSD in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**
 1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
 2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
 3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
 4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
 5. Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:** fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

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INDICATIONS & IMPORTANT SAFETY INFORMATION (CONT'D)



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injection for intravenous use
300 mg/3 mL vial

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start ULTOMIRIS right away and are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

ULTOMIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Certain people may be at risk of serious infections with gonorrhea.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS.

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever
- are pregnant or plan to become pregnant. It is not known if ULTOMIRIS will harm your unborn baby.
 - Pregnancy Registry: There is a registry for pregnant women who take ULTOMIRIS to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ULTOMIRIS, talk to your healthcare provider about how you can join this registry or you may contact the registry at 1-833-793-0563 or www.UltomirisPregnancyStudy.com to enroll.
- are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, stomach (abdominal) pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, or bad taste. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion-related reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

The most common side effects of ULTOMIRIS in people with gMG are diarrhea and upper respiratory tract infections.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information throughout and the accompanying full **Prescribing Information** and **Medication Guide** for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.

ULTOMIRIS[®] IS

moving forward with
proven symptom control*†

*Symptoms were assessed throughout the 26-week trial by the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, which assesses the impact of gMG on daily functions (through 8 signs and symptoms that are typically affected in gMG).

†Many patients continued taking other medications for gMG throughout the 26-week study.

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

A OneSource Specialist can help you get your vaccinations and find an infusion center. Call OneSource at **1-877-GMG-ULTO (877-464-8586)**. Or for questions about gMG, find a PEM at www.mygmgpem.com.

Image is not of an actual patient.

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



In gMG, C5 enables the buildup of proteins that can lead to muscle damage. **ULTOMIRIS blocks C5.**



By targeting C5, ULTOMIRIS may also lower the ability of your immune system to fight meningococcal infections, so **it is necessary to complete or update your meningococcal vaccinations at least 2 weeks before starting treatment.**



It can take up to 6 months to receive the meningococcal vaccinations. Starting the vaccination process early may help ensure you're ready to start ULTOMIRIS.



If you have any signs or symptoms of a serious meningococcal infection, or are unsure, call your healthcare provider or get emergency medical care right away.

gMG, generalized myasthenia gravis; PEM, Patient Education Manager.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#) and [Medication Guide](#) for ULTOMIRIS, including **Boxed WARNING** regarding serious meningococcal infections.