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

The only long-acting gMG treatment with 8 weeks of freedom between infusions*

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

*Maintenance dosing starts 2 weeks after initial dose.

†Based on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, which assesses the impact of MG on 8 activities of daily living and physical functions.

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

Images are not of actual patients

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

IMPORTANT SAFETY INFORMATION

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

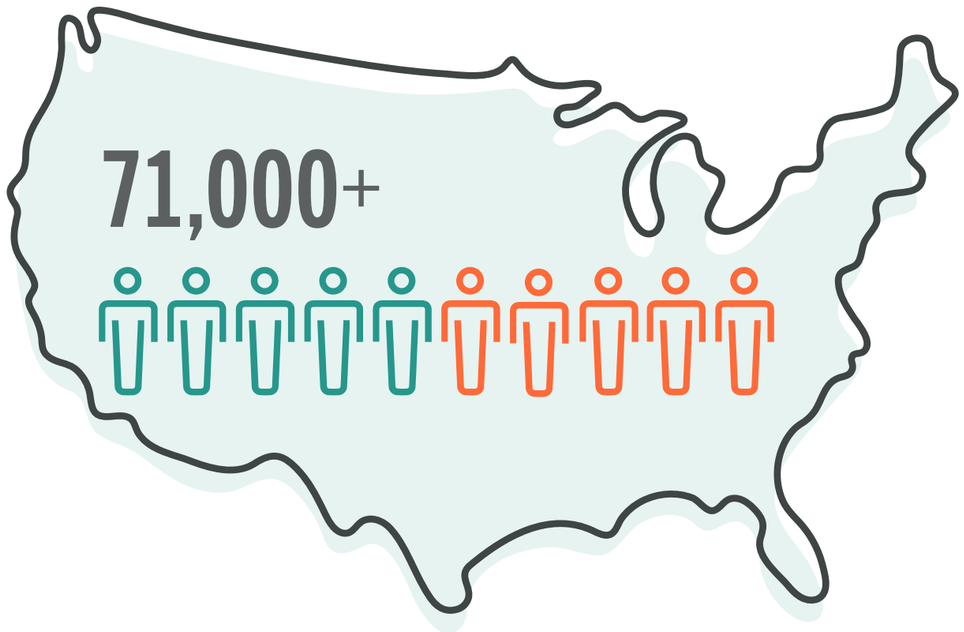
ULTOMIRIS is a medicine that affects your immune system and can lower the ability of your immune system to fight infections.

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

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

gMG is a rare autoimmune disease that impacts the neuromuscular system

It is estimated that **more than 71,000** people in the United States are living with anti-AChR antibody-positive gMG.



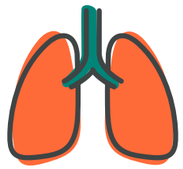
In a 2019 study, **50% of participants reported still experiencing gMG symptoms** that limited their daily life.

Muscle weakness caused by gMG can make daily activities and physical functions challenging

Stress and changes in the weather may trigger symptoms, which can occur at any time and make daily planning more difficult.

Vision

For many people, double vision and drooping eyelids are the first symptoms of gMG. Vision problems may impact your ability to drive, read, or watch TV.



Breathing

When gMG damages the muscles of your diaphragm, you may experience trouble breathing. Breathing impairment may impact your ability to speak or move around.

Speech

gMG can make it hard to speak or may cause you to slur your words. Speech difficulties may make it tough for those around you to understand what you are saying.

Eating

Muscle weakness associated with gMG can make it harder to swallow or hold your head up. Eating difficulties may impact your ability to go out to eat or even eat alone.

Mobility

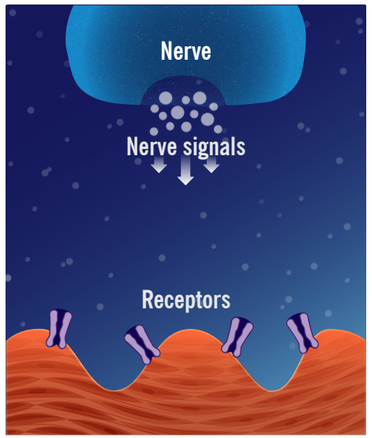
gMG may cause you to experience weakness in your arms and/or legs. Muscle weakness can make personal grooming, household chores, and traveling more difficult to do.

Many people still struggle with gMG symptoms despite available treatments

ULTOMIRIS® in the body

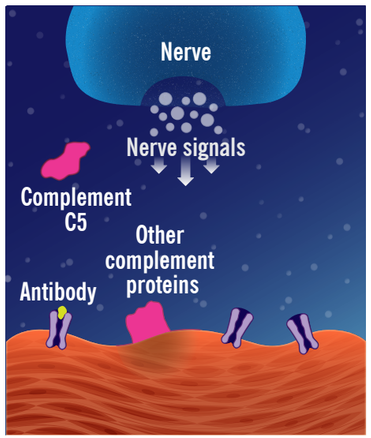
Though the exact manner in which it works as a treatment for gMG is unknown, **ULTOMIRIS is proven to bind to and block C5**, a protein within a part of your immune system called “complement.” If you have gMG, complement incorrectly attacks your muscles.

Healthy Muscle Cell



When a healthy person wants to move their body, muscles receive signals from their nerves. But in gMG, damage happens to the neuromuscular junction, which is where the nerves and muscles meet.

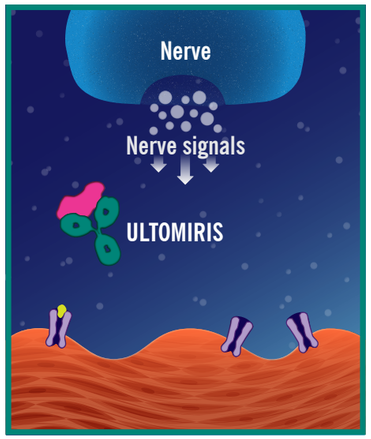
Damaged Muscle Cell



When you have gMG, anti-AChR antibodies block your receptors on your muscles, which causes a part of your immune system called “complement” to incorrectly attack your own muscle cells. C5—a key protein within the complement system—activates other complement proteins, which then directly attack your muscle cells.

This results in damage and inflammation that interrupt your nerve signals, causing gMG symptoms like the muscle weakness you may feel.

Muscle Cell in Treatment



Though the exact way it works as a treatment for gMG is unknown, **ULTOMIRIS is a C5 inhibitor—it binds to and blocks C5**, which is part of the complement system that contributes to damaging your muscle cells in gMG.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

1. You must receive meningococcal vaccines at least 2 weeks before your first dose of ULTOMIRIS if you are not vaccinated.
2. If your healthcare provider decided that urgent treatment with ULTOMIRIS is needed, you should receive meningococcal vaccination as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

4. If you had a meningococcal vaccine in the past, you might need additional vaccination. Your healthcare provider will decide if you need additional vaccination.

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IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

5. Meningococcal vaccines reduce but 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: headache with nausea or vomiting, headache and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms and eyes sensitive to light.

ULTOMIRIS® was studied in a clinical trial (CHAMPION-MG) that included adults with varying degrees of severity of gMG

The 26-week trial measured the impact of ULTOMIRIS on activities of daily living and muscle weakness. It included 175 people who were randomly split into 2 groups: those receiving ULTOMIRIS (86 people) and those receiving placebo (89 people).*

A patient-reported questionnaire
measured the effects of gMG symptoms on activities of daily living

A doctor-reported questionnaire
measured muscle weakness

After Week 26 of the trial, all study participants were eligible to receive ULTOMIRIS for up to an additional 4 years

- Over 90% of people in the trial had mild or moderate gMG†
- If study participants were receiving immunosuppressive therapies at the start of the study, they were required to continue receiving them throughout the initial study period. In fact, at their first dose of ULTOMIRIS, most people were taking an immunosuppressive therapy

Many different kinds of people were studied in the ULTOMIRIS trial. **Ask your healthcare provider if ULTOMIRIS could be right for you**

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

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

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

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

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

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ULTOMIRIS® was proven to provide lasting control over gMG symptoms

Symptom improvements at Week 26:

2×

More than 2x greater improvement in activities of daily living such as*:

Seeing
Chewing
Breathing
Brushing teeth
Combing hair
Rising from a chair

3×

More than 3x greater reduction in muscle weakness, improving physical functions such as†:

Eye and facial movements
Swallowing
Speaking
Hand gripping
Head lifting
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. The MG-ADL scale is a patient-reported symptom improvement scale that was used in the ULTOMIRIS study to measure the difficulty of everyday activities. MG-ADL total scores range from 0 to 24, with higher scores indicating more severe gMG symptoms. In the study, the average baseline total score for people receiving ULTOMIRIS was 9.1; for people receiving placebo, it was 8.9. At Week 26, the average change in score from baseline was -3.1 for people receiving ULTOMIRIS and -1.4 for those receiving placebo.

†Versus placebo from baseline to Week 26 of the clinical trial, according to the Quantitative Myasthenia Gravis (QMG) scale. The QMG scale is a doctor-reported symptom improvement scale. It was used in the ULTOMIRIS study to measure muscle weakness and the difficulty of certain movements. QMG total scores range from 0 to 39, with higher scores indicating more severe gMG symptoms. In the study, the average baseline total score for people receiving ULTOMIRIS was 14.8; for people receiving placebo, it was 14.5. At Week 26, the average change in score from baseline was -2.8 for people receiving ULTOMIRIS and -0.8 for those receiving placebo.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

ULTOMIRIS is only available through a program called the ULTOMIRIS REMS. Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the ULTOMIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a **Patient Safety Card** about the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with a meningococcal vaccine, and if needed, get revaccinated with the meningococcal vaccine. Ask your healthcare provider if you are not sure if you need to be revaccinated.

ULTOMIRIS may also increase the risk of other types of serious infections. Call your healthcare provider right away if you have any new signs or symptoms of infection.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

Who should not receive ULTOMIRIS?
Do not receive ULTOMIRIS if you have a meningococcal infection or have not been vaccinated against meningococcal infection unless your healthcare provider decides that urgent treatment with ULTOMIRIS is needed.

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

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ULTOMIRIS® offers 8 weeks of freedom between infusions*

ULTOMIRIS is delivered by intravenous infusion, with each taking less than 1 hour for most people†

1 infusion once every 8 weeks (just 6-7 times per year)

&

1 hour or less per infusion for most people

ULTOMIRIS dosing gives you
more time to do what you love

ULTOMIRIS REMS

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

Before you can receive ULTOMIRIS, your healthcare provider must:

- enroll in the ULTOMIRIS REMS program
- counsel you about the risk of meningococcal infection
- give you information about the symptoms of meningococcal infection

*Starting 2 weeks after your initial dose.

†Minimum infusion times for ULTOMIRIS 100 mg/mL maintenance doses range from 30 minutes to less than 1 hour, depending on body weight. If a side effect occurs during the infusion of ULTOMIRIS, the infusion may be slowed or stopped by the healthcare provider. After your infusion, your care team will monitor you for at least an additional hour for infusion-related reactions.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

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, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

At least 2 weeks before starting ULTOMIRIS, you must be vaccinated for meningococcal infection

Your healthcare provider or nurse will make sure you receive these vaccines

ULTOMIRIS can lower the ability of your immune system to fight some infections. Before taking ULTOMIRIS, you must be vaccinated against meningococcal infection, a severe and life-threatening infection that can occur in the blood and that requires immediate medical attention.

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 until 2 weeks after vaccination.

If you had a meningococcal vaccine in the past, you might need a booster dose before starting ULTOMIRIS.

Your healthcare provider will decide if you need a booster dose for meningococcal infections.

Vaccination reduces, but does not eliminate, the risk of 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:

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

Carry your Patient Safety Card

Your healthcare provider will give you a Patient Safety Card about the risk of 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 or nurse who treats you. This will help them diagnose and treat you quickly.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

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.

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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 ≥10% of people taking ULTOMIRIS were diarrhea and upper respiratory tract infection

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

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, tiredness, feeling faint, discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider or nurse right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

If gMG symptoms are still impacting you, speak up and ask your healthcare provider about starting ULTOMIRIS

Consider asking your healthcare provider:

- Am I eligible for treatment with ULTOMIRIS?
- How do I take ULTOMIRIS?
- How can I get started on treatment with ULTOMIRIS?
- What are the most common side effects of ULTOMIRIS?
- What resources and financial support options are available if I start ULTOMIRIS?

With ULTOMIRIS, you may expect:

- To receive meningococcal vaccines at least 2 weeks before your first ULTOMIRIS dose if not already vaccinated. If you're not vaccinated and ULTOMIRIS is urgent, you should also receive 2 weeks of antibiotics with your vaccines
- To have infrequently scheduled maintenance dosing just once every 8 weeks after your initial dose*
- To have an infusion of ULTOMIRIS (less than 1 hour for most people) and to be monitored for at least 1 hour after each infusion†
- To experience certain common side effects such as diarrhea or upper respiratory tract infection
- To see lasting control over your gMG symptoms‡

Visit https://ULTOMIRISgmg.com/resources to access a gMG questionnaire that you can use to keep track of your symptoms. Then, share your results with your healthcare provider at your next visit.

*Maintenance dosing begins 2 weeks after your initial dose.

†Minimum infusion times for ULTOMIRIS 100 mg/mL maintenance doses range from 30 minutes to less than 1 hour, depending on body weight. If a side effect occurs during the infusion of ULTOMIRIS, the infusion may be slowed or stopped by the healthcare provider.

‡Based on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, which assesses the impact of MG on 8 activities of daily living and physical functions.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

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

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We're here to help!

Learn about support services available to you through OneSource™, a free, personalized patient support program offered by Alexion

ONESOURCE®

Personalized Patient Support from Alexion

We can help with:

Education

Learn more about your condition and treatment with ULTOMIRIS®.

Community Connections

Find events and resources, like a helpful peer-to-peer program called Peer Connects.

Ongoing Support

Navigate life and insurance changes, as well as vaccine requirements, to ensure you receive your medicine as prescribed.

Health Insurance Navigation

Get help with financial concerns or gaps in coverage.

Visit AlexionOneSource.com for more information about patient support for ULTOMIRIS. You can also contact OneSource at 1-888-765-4747.

ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). To learn more, visit ULTOMIRISrems.com

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING & INDICATION

INDICATION

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat adults with a disease called generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

It is not known if ULTOMIRIS is safe and effective for the treatment of gMG 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 can lower the ability of your immune system to fight infections.

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3. If you have not been vaccinated and ULTOMIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
4. If you had a meningococcal vaccine in the past, you might need additional vaccination. Your healthcare provider will decide if you need additional vaccination.
5. Meningococcal vaccines reduce but 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: headache with nausea or vomiting, headache and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms and eyes sensitive to light.

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

ULTOMIRIS is only available through a program called the ULTOMIRIS REMS. Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the ULTOMIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a **Patient Safety Card** about the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with a meningococcal vaccine, and if needed, get revaccinated with the meningococcal vaccine. Ask your healthcare provider if you are not sure if you need to be revaccinated.

ULTOMIRIS may also increase the risk of other types of serious infections. Call your healthcare provider right away if you have any new signs or symptoms of infection.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a meningococcal infection or have not been vaccinated against meningococcal infection unless your healthcare provider decides that urgent treatment with ULTOMIRIS is needed.

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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.

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

ULTOMIRIS®

lasting control over your **gMG** symptoms* & doing what matters most

Visit **ULTOMIRISgmg.com** and ask your healthcare provider if ULTOMIRIS is right for you

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

Images are not of actual patients

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ALEXION®
AstraZeneca Rare Disease