

INDICATION & IMPORTANT SAFETY INFORMATION

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.

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.



Despite available treatments, 50% of the people in a 2019 study reported still experiencing gMG symptoms that limited their everyday life.

Since gMG is a chronic rare disease, it's important to find a treatment that can help you manage it over time

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



Vision



Breathing



Speech



Eating



Mobility

Common treatments for gMG include steroids and immunosuppressive therapies



Many people use steroids to treat their gMG, but long-term steroid use may cause serious side effects.

As gMG symptoms can worsen in the first 2 years, the first step is to talk to your doctor about a plan for managing your gMG symptoms

(ravul injection 30

ULTOMIRIS[®] is proven to provide continuous control over gMG symptoms

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



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

Seeing

Chewing

Breathing

Brushing teeth

Combing hair

Rising from a chair



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

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

SELECT IMPORTANT SAFETY INFORMATION

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

^{*}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 trial, the 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 score from baseline was -3.1 points for people receiving ULTOMIRIS and -1.4 for those receiving placebo. Many people continued taking other medicines throughout the trial.

[†]Versus placebo from baseline to Week 26 of the clinical trial, according to the Quantitative Myasthenia Gravis (QMG) scale. In the trial, 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 score from baseline was -2.8 points for people receiving ULTOMIRIS and -0.8 for those receiving placebo. Many people continued taking other medicines throughout the trial.



Additional data for ULTOMIRIS®

Medicines are studied in clinical trials to find out if they can help people effectively and safely

Clinical trials—like the one in which ULTOMIRIS was studied—have a few specific goals that are decided before they begin.

• The results below were not preplanned study goals, so no conclusions can be drawn. Talk with your healthcare team about any questions you may have

Alexion is committed to the continued analysis of trial data to better understand the treatment of gMG.

People who started ULTOMIRIS within 2 years of gMG diagnosis experienced 4.3 points of improvement in MG-ADL total score at Week 26, vs 2.9 points for people who started ULTOMIRIS more than 2 years after diagnosis.

Of 175 people in the trial, 35 started the trial within 2 years of gMG diagnosis (19 received ULTOMIRIS) and 140 started more than 2 years after diagnosis (67 received ULTOMIRIS).

82% of people experienced at least 3 points of improvement with ULTOMIRIS by Week 60 of the clinical trial.

At Week 60 (34 weeks after people who received placebo in the initial 26 weeks of the clinical trial had switched to ULTOMIRIS, and after those receiving ULTOMIRIS had continued to take it for an additional 34 weeks), their data up to that point were collected for analysis. Of the 139 people who stayed in the study until that time point, 82% had at least 3 points of improvement in MG-ADL total score.

The extension period was designed to measure safety, so no conclusions should be drawn.

Individual results may vary.

Not everyone who takes ULTOMIRIS will experience the same results.

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.



SELECT IMPORTANT SAFETY INFORMATION

- **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.



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)*

- The MG-ADL scale measured the effects of gMG symptoms on activities of daily living and physical functions
- The QMG scale measured muscle weakness
- Over 90% of people in the trial had mild or moderate gMG[†]
- At their first dose of ULTOMIRIS, most people were taking an immunosuppressive therapy. If people were receiving immunosuppressive therapies at the start of the trial, they were required to continue taking them at stable doses throughout the initial trial 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

How were these results measured?

The Myasthenia Gravis Activities of Daily Living (MG-ADL) scale is a patient-reported symptom improvement questionnaire that was used in the ULTOMIRIS trial to **measure the impact of gMG symptoms** on 8 key daily activities and functions. MG-ADL total scores range from 0 to 24, with **higher scores indicating more severe gMG symptoms**.

Another questionnaire called the **Quantitative Myasthenia Gravis (QMG)** scale was also used in the ULTOMIRIS trial. The QMG scale is a 13-item doctor-reported symptom improvement scale that **assesses muscle weakness**. QMG total scores can range from 0 to 39, with **higher scores indicating more severe gMG symptoms**.

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

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

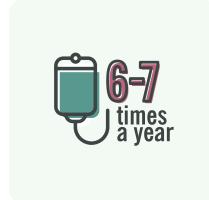
SELECT IMPORTANT SAFETY INFORMATION

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.



ULTOMIRIS® offers the freedom of just 6-7 infusions per year*

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





8 weeks between each infusion, starting 2 weeks after an initial dose





We love to travel. ULTOMIRIS dosing gave me the freedom I wanted to have with my vacation schedules.

Mike

Real ULTOMIRIS Patient

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

Mike has a family member who is employed by Alexion, including at the time Mike started treatment.



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.

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.

^{*}Starting 2 weeks after an initial dose.



After your initial dose, with just 6-7 infusions per year lasting less than 1 hour each for most people, ULTOMIRIS® gives you more time to do what you love

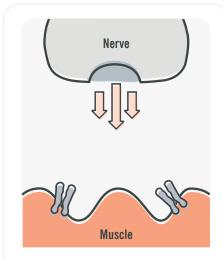
SELECT IMPORTANT SAFETY INFORMATION

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.

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

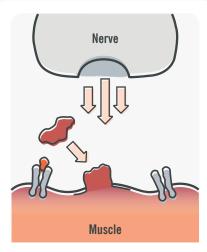
As the first long-acting C5 inhibitor for gMG, ULTOMIRIS blocks C5—a key protein that contributes to muscle damage

In gMG, muscle function is lost when a faulty immune response mistakenly attacks muscle cells; this is activated in part by a key protein called C5. ULTOMIRIS blocks C5



Healthy Muscle Cell

Normally, nerves send signals to special receptors on the muscles in order to trigger body movements.

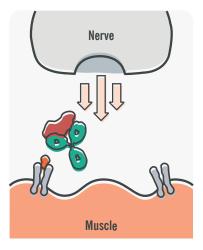


Muscle Cell With gMG

In anti-AChR antibodypositive 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.

C5—a key protein within the immune system—enables the buildup of related proteins on the surface of the muscle.

This results in muscle cell damage, which may cause gMG symptoms like the muscle weakness or difficulties with movement that are commonly experienced.



Muscle Cell in Treatment With ULTOMIRIS

ULTOMIRIS is the first and only long-acting C5 inhibitor—it binds to and blocks C5, a key protein that contributes to muscle damage in gMG. ULTOMIRIS blocks C5 immediately and completely.

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

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.



Learn about key players in anti-AChR antibody-positive gMG



Movement signals

Normally, nerves send signals to special receptors on the muscles in order to trigger body movements. But gMG can damage this connection and make muscle movement more difficult.



Receptor

Muscle cell receptors receive signals from nerves and help translate them into muscle movements.



Antibody-blocked receptor

In gMG, antibodies block receptors, triggering an attack from the immune system on the muscle cells it normally protects.



Protein C5

C5—a key protein within the immune system—enables the buildup of related proteins on the surface of the muscle.



ULTOMIRIS

ULTOMIRIS binds to and blocks C5 immediately and completely.

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

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.

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.



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

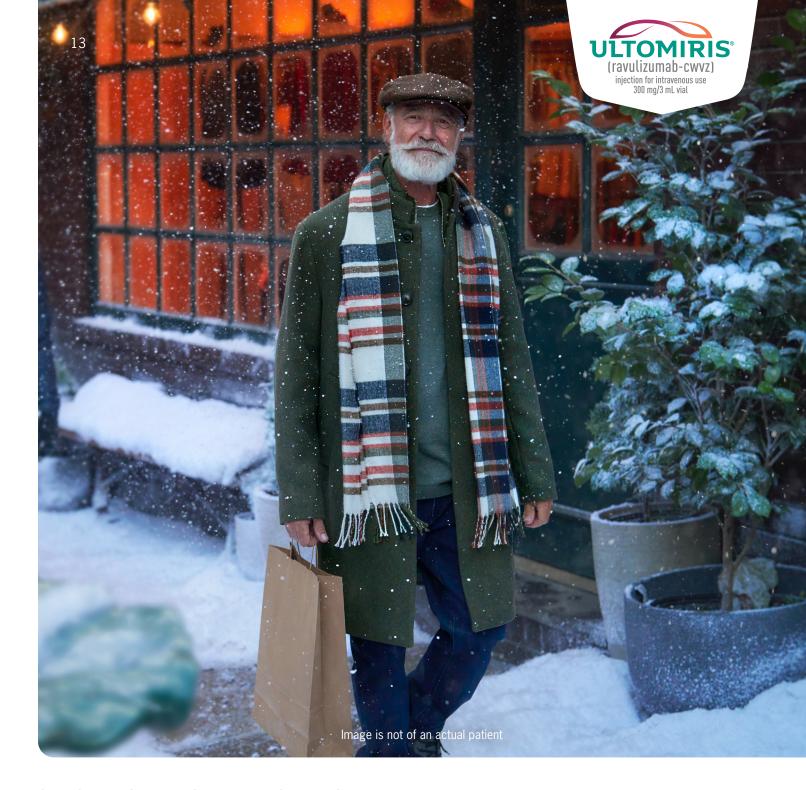
The following side effects were experienced by 5% or more of people in the trial and at a greater frequency with ULTOMIRIS vs placebo

	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

SELECT IMPORTANT SAFETY INFORMATION

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.



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.

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, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, bad taste, or drowsiness.



If you still feel limited by your gMG symptoms, ask your doctor about starting ULTOMIRIS®

Questions to ask at your next appointment:

- Am I eligible for treatment with ULTOMIRIS?
- How do I take ULTOMIRIS?
- Where do I receive treatment with ULTOMIRIS?
- What are the most common side effects of ULTOMIRIS?
- What resources and financial support options are available to me if I start ULTOMIRIS?

When you're being treated with ULTOMIRIS, you may expect:

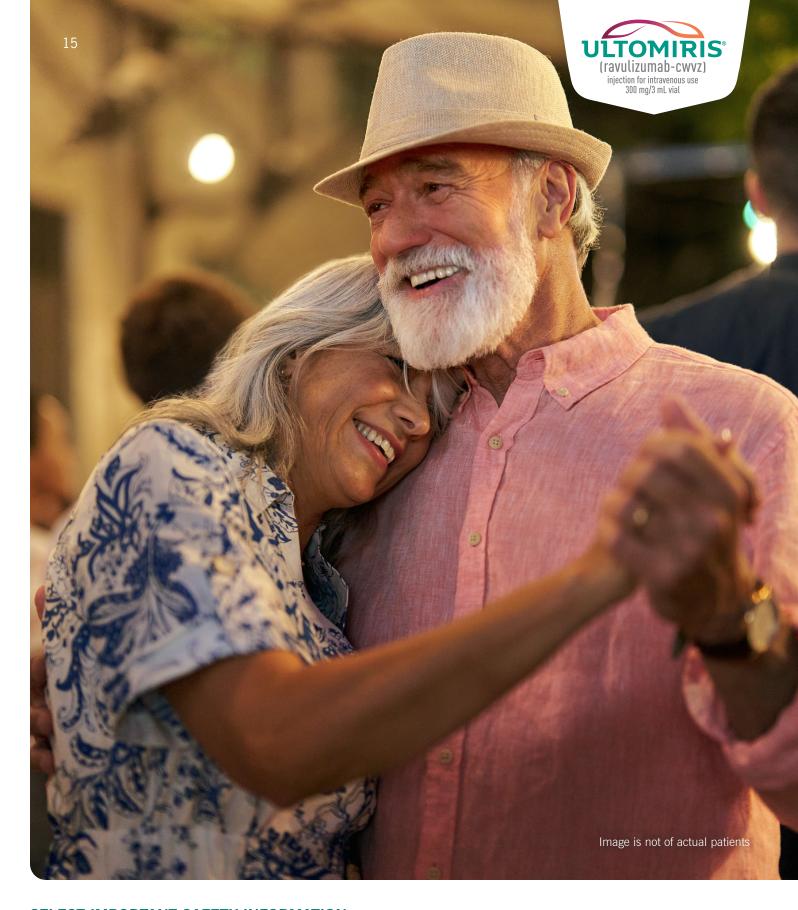
- To receive meningococcal vaccines as part of a required proactive plan. The vaccine does not eliminate the risk of meningococcal infection, which may be higher because ULTOMIRIS works directly on the immune system. If you're not vaccinated and ULTOMIRIS is needed urgently, you should also receive antibiotics with your vaccines for as long as your healthcare provider tells you
- To have scheduled maintenance dosing once every 8 weeks, starting 2 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 track improvement over your gMG symptoms

To view the gMG symptom tracker that you can use to keep track of your symptoms, visit **<u>ULTOMIRISgmg.com/resources</u>**. Then, share your results with your healthcare provider at your next visit.

*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.

SELECT IMPORTANT SAFETY INFORMATION

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.



SELECT IMPORTANT SAFETY INFORMATION

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



You must receive meningococcal vaccines at least 2 weeks before starting ULTOMIRIS®

Your healthcare provider will make sure you receive these vaccines as part of a required proactive plan



Before starting on ULTOMIRIS, you will receive meningococcal vaccines. The vaccine does not eliminate the risk of meningococcal infection, which may be higher because ULTOMIRIS works directly on the immune system.

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.

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.

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 serious meningococcal infection:

- 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

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about any side effect that bothers you or that does not go away.



REMS Program

ULTOMIRIS® is available only through a restricted program called the 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 you are not up to date on your vaccines
- give you a Patient Safety Card about your risk of meningococcal infection, as discussed below



Carry your Patient Safety Card

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.



My neurologist told me about ULTOMIRIS. I followed the research and...started the process of changing my treatment. My doctor and I timed the change so there wouldn't be any lapse in treatment.

Real ULTOMIRIS Patient Who Switched From SOLIRIS®

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

Mike has a family member who is employed by Alexion, including at the time Mike started treatment.



SELECT IMPORTANT SAFETY INFORMATION

These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist.



We're here to help!

Enroll in support services available to you through OneSource[™], a free, personalized patient support program offered by Alexion



Our support specialists partner with you to help with:

- Navigating health insurance, financial concerns, or gaps in coverage, including information about the Alexion OneSource CoPay Program
- Providing support for **meningococcal vaccinations** before starting your treatment
- Offering education about your condition and treatment with ULTOMIRIS®
- Creating community connections through events and resources like our helpful peer-to-peer program,
 Peer Connects
- Providing ongoing support to ensure you receive your medicine as prescribed, including logistics with infusion centers and doctor's offices

Pay as little as \$0 for ULTOMIRIS if you have commercial insurance*

*Subject to Terms & Conditions at http://AlexionOneSource.com/allpay
Additional eligibility requirements apply

Find your Alexion Patient Education Manager

Understanding your disease is important. A Patient Education Manager (PEM) is a local partner who can help empower you with educational resources and community connections throughout your gMG treatment journey.

If you have any questions about treatment or support with ULTOMIRIS, don't hesitate to reach out to your PEM.

To view more information about patient support for ULTOMIRIS, you can contact OneSource at <u>1-877-GMG-ULTO (877-464-8586)</u> or visit <u>AlexionOneSource.com</u>.

SELECT IMPORTANT SAFETY INFORMATION

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 <u>1-800-FDA-1088</u>.



INDICATION & IMPORTANT SAFETY INFORMATION

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 may lower the ability of your immune system to fight infections.

- ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become lifethreatening 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.

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.

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

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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, 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.

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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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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