

A guide to discussing ULTOMIRIS with your neurologist Explore information and ideas to help you start ULTOMIRIS for gMG

The first and only long-acting C5 inhibitor

FDA approved to treat
4 rare autoimmune diseases,
including anti-AChR
antibody-positive gMG

Can be taken with or without steroids

FDA, Food and Drug Administration.

INDICATION & IMPORTANT SAFETY INFORMATION

INDICATION

What is ULTOMIRIS?

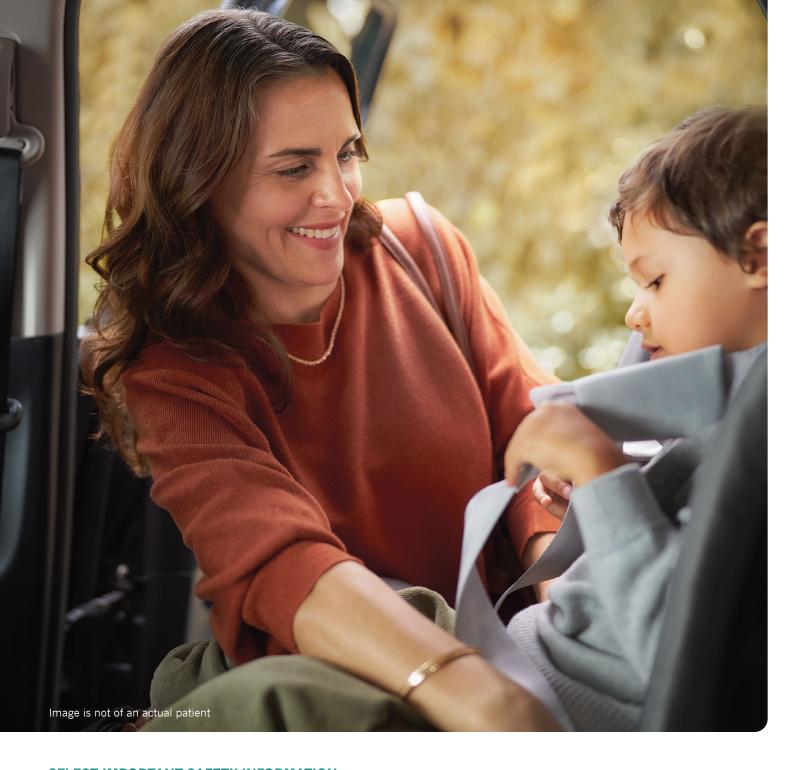
ULTOMIRIS is a prescription medicine used to treat adults with a disease called generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. It is not known if ULTOMIRIS is safe and effective for the treatment of gMG in children.

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 life-threatening or cause death if not recognized and treated early.



SELECT IMPORTANT SAFETY INFORMATION

- **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.



Reflect on your gMG experience and prepare to discuss your treatment goals by answering the questions below

1	I was diagnosed with anti-AChR antibodypositive gMG Less than 1 year ago 1-2 years ago More than 2 years ago	4	On a scale from 1-10, with 1 being "least satisfied" and 10 being "most satisfied," circle the number that represents how satisfied I am with my current gMG treatment. 1 2 3 4 5 6 7 8 9 10			
2	I'm affected by gMG symptoms like Slurred speech	5	What am I looking for in a gMG treatment? Select all that apply:			
	Muscle fatigue		Continuous symptom control			
	Trouble chewing		A predictable and less frequent dosing schedule			
	Trouble swallowing		Manageable side effects			
	Trouble breathing		May minimize the need for other gMG treatments			
	Impaired motion		Other:			
	Double vision					
	Eyelid droop					
	Other:					
3	How often am I affected by my gMG symptoms?					
	Less than once per day					
	About once per day					
	More than once per day					

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.





Bring up your MG-ADL score when your doctor asks how you've been feeling. Even just mentioning that you've taken it can help start the conversation about ULTOMIRIS

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.



Myasthenia Gravis Activities of Daily Living (MG-ADL)

It's important to measure your generalized myasthenia gravis symptoms over time. Fill out this form and share the results with your doctor so they can better understand how your symptoms are impacting you.

- Score each activity from 0-3 and add the results to see your total score
- Complete form regularly (for example, every 3 months) or as instructed by your doctor

Reflecting with a caregiver or friend can help you with these answers

	0=Normal	1	2	3=Most severe
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal speech, but can be understood	Difficult-to- understand speech
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant
				Total score
Patient name	e		Da	te to re-evalu
Date /		//		
		ttps://myasthenia.org/Port		

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

healthcare providers. It does not replace a healthcare provider's independent medical

judgment or clinical diagnosis.



Now that you're familiar with the MG-ADL, don't wait to ask your doctor if ULTOMIRIS® is right for you

Having a conversation about your gMG treatment can be challenging. Some questions that you may want to consider asking your doctor include:



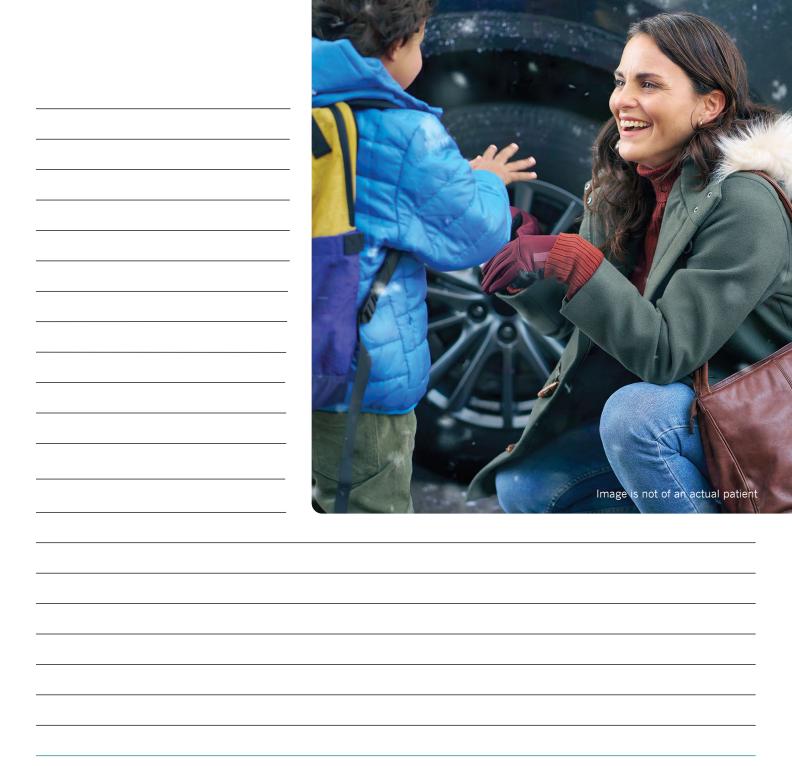
- Am I eligible for treatment with ULTOMIRIS?
- Is ULTOMIRIS right for me?
- How can I get started on ULTOMIRIS?
- What are the most common side effects of ULTOMIRIS?
- What is a meningococcal vaccine and why do I have to take it?
- Where do I receive ULTOMIRIS?

Have any questions or ideas of your own? Use the space below to record them so you're ready to discuss ULTOMIRIS with your doctor						

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.





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.



Have questions about treating your gMG with ULTOMIRIS®? We've got answers

How can ULTOMIRIS help me manage my gMG?

In a clinical trial, ULTOMIRIS was 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 function such as:

Eye and facial movements

Swallowing

Speaking

Hand gripping

Head lifting

Limb stretching

The most common side effects are diarrhea and upper respiratory tract infections.

*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 impact of gMG symptoms on 8 key daily functions. 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 the 86 people receiving ULTOMIRIS was 9.1; for the 89 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. 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. 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. In the study, the average baseline total score for the 86 people receiving ULTOMIRIS was 14.8; for the 89 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. Many people continued taking other medicines throughout the study.

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.

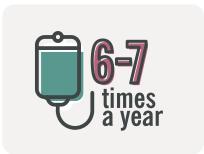
Who should not receive ULTOMIRIS?

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



How do I take ULTOMIRIS®?

ULTOMIRIS offers the freedom of just 6-7 intravenous infusions per year. Each infusion takes about 1 hour or less for most people.*







How was ULTOMIRIS studied?

ULTOMIRIS was studied in a wide range of people. The clinical trial measured the impact of ULTOMIRIS on daily activities and muscle weakness over 26 weeks. It included 175 people who were randomly split into 2 groups: those taking ULTOMIRIS (86 people) and those receiving placebo (89 people).[†]

To learn more about clinical results with ULTOMIRIS, visit www.ultomiris.com/gmg/clinical-results-with-ultomiris

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

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, 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.



^{*}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.

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

*Additional eligibility criteria apply. See Terms and Conditions available at https://AlexionOneSource.com/allpay.

Your doctor can help you enroll in OneSource™, a free and personalized patient support program offered by Alexion that can help with financial and logistical concerns

Alexion OneSource 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 vaccination** before your first dose and throughout treatment with ULTOMIRIS
- 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

Learn more about savings and affordability with ULTOMIRIS

To discover savings and support with ULTOMIRIS, visit www.ULTOMIRIS.com/gmg/cost-and-savings

Find your Patient Education Manager (PEM)

Understanding your disease is important. A PEM is a local partner who can help empower you with 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.

Visit <u>www.AlexionOneSource.com/ULTOMIRIS/find-your-patient-education-manager</u> to connect.



Want to learn more about support with OneSource? Call a PEM at 1-877-GMG-ULTO (877-464-8586)



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

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- 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.
 - 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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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, 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.

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. 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 the accompanying full <u>Prescribing</u> <u>Information</u> and <u>Medication Guide</u> for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.





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 to take 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 see continuous control over your gMG symptoms

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