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

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

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

1. You must receive meningococcal vaccines at least 2 weeks before your first dose of SOLIRIS unless you have already had this vaccine. If your doctor decided that urgent treatment with SOLIRIS is needed, you should receive meningococcal vaccination as soon as possible.

2. If you had a meningococcal vaccine in the past, you might need additional vaccination before starting SOLIRIS. Your doctor will decide if you need additional meningococcal vaccination.

3. Meningococcal vaccines do not prevent all meningococcal infections. Call your doctor 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 with a stiff neck or stiff back
- fever and a rash
- muscle aches with flu-like symptoms

- headache and a fever
- fever
- confusion
- eyes sensitive to light

Please see Important Safety Information on page 7 and back cover. Please see accompanying full Prescribing Information and Medication Guide for Soliris, including boxed WARNING regarding serious meningococcal infection.
Soliris® (eculizumab) is for adults with anti-AchR+ gMG

There are several types of antibodies that cause gMG, the most common of which is the anti-acetylcholine receptor (AchR) antibody. It is important to know which type you have so that you and your doctor can come up with the best care plan for you.

Speak with your doctor about which antibody type causes your gMG. If your gMG is anti-acetylcholine receptor antibody positive (anti-AchR+), Soliris may be able to help.

Together with your doctor and caregivers, you have faced the unpredictability of gMG—a rare autoimmune disease that can cause you to feel symptoms of muscle weakness and fatigue and can affect daily activities such as breathing, swallowing, seeing, talking, or walking. In addition to daily unresolved symptoms, you may experience exacerbations, or sudden and dangerous worsening of symptoms, that require you to see a doctor or visit the hospital.

MG, at its worst, disrupts every part of a person’s life. It’s hard to do daily activities—it can be even hard to get out of bed and employment is out of the question.

— Nancy Law, CEO of Myasthenia Gravis Foundation of America

Both anti-AchR antibodies and complement play key roles in your gMG

Nerves communicate with muscles at a site called the neuromuscular junction (NMJ). Normally, nerves release acetylcholine, a molecule that signals the muscle to start contracting. In some patients with gMG, anti-AchR antibodies disrupt communication by blocking these signals and activating a process involving complement—a part of the immune system that, in healthy bodies, helps fight bacteria and other threats. In gMG, active complement is the primary cause of symptoms of muscle weakness and fatigue.

The role of complement in anti-AchR+ gMG

1. **Complement initiation.** In anti-AchR+ gMG, antibodies bind to receptors (AchR) and disrupt nerve-to-muscle communication. They also cause complement to act at the NMJ, the site where nerves communicate with muscles.

2. **Ongoing injury.** At the NMJ, complement continually injures the muscle surface, which is critical for nerve-to-muscle communication.

3. **Consequences.** When the muscle surface is injured, some AchRs are lost, further decreasing nerve-to-muscle communication, which contributes to symptoms of muscle weakness and fatigue.

SOLIRIS is only available through a program called the SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive SOLIRIS, your doctor must:

- enroll in the SOLIRIS REMS program
- counsel you about the risk of meningococcal infection
- give you information about the symptoms of meningococcal infection
- give you a Patient Safety Card about your risk of meningococcal infection
- make sure that you are vaccinated with a meningococcal vaccine

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What is Soliris® (eculizumab) and how does it work?

Soliris is a type of treatment called a monoclonal antibody that is thought to reduce the activity of complement at the muscle surface in patients with anti-AchR+ gMG.

Soliris at work in anti-AchR+ gMG

Soliris attaches to a complement protein at a key moment, reducing further activity at the NMJ.

Serious allergic reactions can happen during your Soliris infusion. Tell your doctor or nurse right away if you experience any of these symptoms during your Soliris infusion: chest pain; trouble breathing or shortness of breath; swelling of your face, tongue or throat; or if you feel faint or pass out. If you have an allergic reaction to Soliris, your doctor may need to slow or stop the infusion. After each infusion, you should be monitored for at least 1 hour for allergic reactions.

You must receive meningococcal vaccines at least 2 weeks before your first dose of Soliris.

Tell your doctor right away if you have any of the above symptoms during your Soliris infusion.

In clinical trials, Soliris improved activities of daily living and muscle weakness in patients with gMG

Soliris is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive. In clinical trials, Soliris was shown to improve activities of daily living and muscle weakness in patients with unresolved symptoms, despite multiple treatments. Of patients receiving Soliris:

- 60% reported an improvement in activities of daily living compared with 40% of those taking placebo
- 45% had a clinically meaningful improvement in muscle weakness compared with 19% of those taking placebo

Patients who responded to Soliris had improvement of their gMG symptoms usually within 12 weeks of starting treatment.

SOLIRIS may also increase the risk of other types of serious infections. If your child is treated with SOLIRIS, make sure that your child receives vaccinations against Streptococcus pneumoniae and Haemophilus influenzae type b (Hib).

Who should not receive SOLIRIS?

Do not receive SOLIRIS if you:

- have a meningococcal infection
- have not been vaccinated against meningococcal infection unless your doctor decides that urgent treatment with SOLIRIS is needed. See “What is the most important information I should know about SOLIRIS?”

Please see full Important Safety Information on page 7 and back cover. Please see accompanying full Prescribing Information and Medication Guide for Soliris, including boxed WARNING regarding serious meningococcal infection.

Abbreviations: MG-ADL, MG-activities of daily living; QMG, quantitative MG.

aClinical response defined as ≥3-point improvement from baseline in MG-ADL total score at 26 weeks of treatment.

bClinical response defined as ≥5-point improvement from baseline in QMG total score at 26 weeks of treatment.
Nurse Case Managers at OneSource™ are here to help

Your healthcare team is your best resource when it comes to support and information about your anti-AchR+ gMG. Alexion, the maker of Soliris (eculizumab), provides a complimentary, personalized patient support program called OneSource that is tailored to the specific needs of people living with gMG. Learn more at AlexionOneSource.com.

Important Safety Information

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.
- Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risk of developing a meningococcal infection.
- Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or at www.solirisrems.com.

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  1. You must receive meningococcal vaccines at least 2 weeks before your first dose of SOLIRIS unless you have already had this vaccine. If your doctor decided that urgent treatment with SOLIRIS is needed, you should receive meningococcal vaccination as soon as possible.
  2. If you had a meningococcal vaccine in the past, you might need additional vaccination before starting SOLIRIS. Your doctor will decide if you need additional meningococcal vaccination.
  3. Meningococcal vaccines do not prevent all meningococcal infections. Call your doctor 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 with a stiff neck or stiff back
    - fever and a rash
    - muscle aches with flu-like symptoms
    - fever
    - confusion
    - eyes sensitive to light

Your doctor will give you a Patient Safety Card about the risk of meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last SOLIRIS dose. Your risk of meningococcal infection may continue for several weeks after your last dose of SOLIRIS. It is important to show this card to any doctor or nurse who treats you. This will help them diagnose and treat you quickly.

SOLIRIS is only available through a program called the SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive SOLIRIS, your doctor must:

- enroll in the SOLIRIS REMS program
- counsel you about the risk of meningococcal infection
- give you information about the symptoms of meningococcal infection
- give you a Patient Safety Card about your risk of meningococcal infection
- make sure that you are vaccinated with a meningococcal vaccine

Please see full Important Safety Information on page 7 and back cover.

Please see accompanying full Prescribing Information and Medication Guide for Soliris, including boxed WARNING regarding serious meningococcal infection.
Important Safety Information (continued)

SOLIRIS may also increase the risk of other types of serious infections. If your child is treated with SOLIRIS, make sure that your child receives vaccinations against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib).

**What is SOLIRIS?**

SOLIRIS is a prescription medicine called a monoclonal antibody. SOLIRIS is 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 SOLIRIS is safe and effective in children with gMG.

**Who should not receive SOLIRIS?**

Do not receive SOLIRIS if you:

- have a meningococcal infection
- have not been vaccinated against meningococcal infection unless your doctor decides that urgent treatment with SOLIRIS is needed. See “What is the most important information I should know about SOLIRIS?”

Before you receive SOLIRIS, tell your doctor 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 SOLIRIS will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if SOLIRIS passes into your breast milk

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOLIRIS and other medicines can affect each other, causing side effects.

It is important that you:

- have all recommended vaccinations before you start SOLIRIS
- stay up-to-date with all recommended vaccinations during treatment with SOLIRIS

Know the medications you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

**What are the possible side effects of SOLIRIS?**

SOLIRIS can cause serious side effects including:

- See “What is the most important information I should know about SOLIRIS?”
- **Serious allergic reactions.** Serious allergic reactions can happen during your SOLIRIS infusion. Tell your doctor or nurse right away if you get any of these symptoms during your SOLIRIS infusion:
  - chest pain
  - trouble breathing or shortness of breath
  - swelling of your face, tongue, or throat
  - feel faint or pass out

If you have an allergic reaction to SOLIRIS, your doctor may need to infuse SOLIRIS more slowly or stop SOLIRIS. See “How will I receive SOLIRIS?”

**The most common side effects in people with gMG treated with SOLIRIS include:**

- muscle and joint (musculoskeletal) pain

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

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