



Starting with Soliris® (eculizumab)

INDICATION & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

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.

SELECT IMPORTANT SAFETY INFORMATION

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. *(continued on next page)*

Please see additional Important Safety Information on pages throughout, and the full [Prescribing Information](#) and [Medication Guide](#) for Soliris, including **Boxed WARNING** regarding serious and life-threatening meningococcal infections.

Take on
your day

SOLIRIS[®]
(eculizumab)
Injection for Intravenous Use

SELECT IMPORTANT SAFETY INFORMATION

1. You must receive meningococcal vaccines at least 2 weeks before your first dose of SOLIRIS if you have not already had this vaccine.
2. If your doctor decided that urgent treatment with SOLIRIS is needed, you should receive meningococcal vaccination as soon as possible.
3. If you have not been vaccinated and SOLIRIS 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 before starting SOLIRIS. Your doctor will decide if you need additional meningococcal vaccination.
5. Meningococcal vaccines reduce the risk of meningococcal infection but 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 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

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 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, as discussed above
- make sure that you are vaccinated with a meningococcal vaccine

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). Certain people may be at risk of serious infections with gonorrhea. Talk to your doctor about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing. Certain fungal infections (*Aspergillus*) may also happen if you take SOLIRIS and have a weak immune system or a low white blood cell count.

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

Being prepared can help you have a good start to your treatment journey.

On the following pages, you'll learn valuable tips on how to prepare for treatment, what to expect throughout, and the tools and resources available to help you take on your day.

Treatment support

Connect with OneSource™

OneSource is a complimentary, personalized patient support program.

Your Nurse Case Manager is there to help before, during, and after you start treatment by:

- Answering questions about gMG or Soliris® (eculizumab)
- Assisting with health insurance navigation
- Helping you find local resources or infusion centers when traveling
- Connecting you to others living with gMG
- Supporting you through your gMG journey



To connect with the OneSource Nurse Case Manager Team, you must complete the authorization and enrollment form:

- **At your doctor's office**
- **By calling 1.888.765.4747**
- **By visiting AlexionOneSource.com**

Complete an MG-ADL assessment

A Myasthenia Gravis Activities of Daily Living (MG-ADL) assessment is a way to measure the severity of your gMG symptoms and their impact on your daily activities. Completing one in your doctor's office before starting Soliris can help you and your doctor track your symptoms.

To download the MG-ADL assessment, visit:

www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx

Understand your insurance coverage

Soliris is covered by most commercial and government insurance. To help navigate insurance coverage options, call OneSource at **1.888.765.4747**.

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Before treatment

1 Get meningococcal vaccines

Because of the way Soliris works in the immune system, it's extremely important to make sure you don't leave yourself open to meningococcal infections, which can be serious and life-threatening.

At least 2 weeks prior to your first dose of Soliris, you must receive meningococcal vaccines if you have not already had these vaccines. In most cases, the meningococcal vaccinations can be given at a doctor's office or retail pharmacy.

Meningococcal vaccines reduce the risk of meningococcal infections but do not prevent all meningococcal infections. Call your doctor or get emergency medical care right away if you get any of the signs or symptoms of a meningococcal infection.

Find where to get vaccinated near you at www.vaccines.gov/getting/where.

2 Find an infusion center

Soliris is a treatment that is given by IV infusion. Some people visit an infusion center to receive Soliris while others prefer to have a visiting nurse administer their infusion at home. The location in which you receive your infusion can depend on your insurance and where you live. Contact a OneSource Nurse Case Manager if you have questions.

SELECT IMPORTANT SAFETY INFORMATION

Who should not receive SOLIRIS?

Do not receive SOLIRIS if you:

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

Starting treatment

What to expect at your first infusion

Ask before you arrive

Give your OneSource™ Nurse Case Manager a call. They can tell you more about what to expect before and during your first infusion.

Bring your gMG Treatment Journal

Remember to bring your treatment planner/journal to capture the dates and times of future appointments. Take some time during your infusion to note how you've been feeling.

Plan accordingly

Be sure to arrive early for your appointment to fill out or sign any necessary paperwork. Once your infusion begins, it usually takes about 35 minutes to complete. Afterwards, you'll need to be monitored for at least 1 hour to ensure there are no allergic reactions.

Know the dosing schedule

Dosing occurs in 2 phases. Initially, infusions are given weekly for 4 weeks, followed by a fifth dose 1 week later. Then, ongoing infusions are given every 14 days. Soliris® (eculizumab) is a continuous therapy. Your doctor will discuss the ongoing timeline with you.

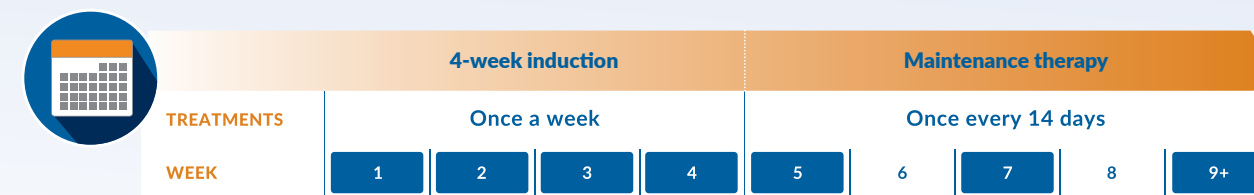
SELECT IMPORTANT SAFETY INFORMATION

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.

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Dosing schedule



Serious allergic reactions can occur 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.

During your infusion

Getting your infusion can take up some time.
Bring a neck pillow or blanket if you like.

- | Rest | Read a book or magazine | Reflect |
|-------------------------------|--------------------------|---|
| Listen to music | Listen to a podcast | Note how you're feeling in your treatment planner/journal |
| Catch up on email or the news | Watch your favorite show | |
| | Do a crossword puzzle | |

Throughout treatment

Stay in touch with OneSource™

OneSource is here for you, no matter how long you've been on treatment. As you continue with treatment, your OneSource Nurse Case Manager can help:

- Navigate changes to your insurance plan
- Answer questions about gMG
- Connect you with other people in your community who are living with gMG



Call 1.888.765.4747 to connect with the OneSource Nurse Case Manager Team.

SELECT IMPORTANT SAFETY INFORMATION

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
- receive 2 weeks of antibiotics if you immediately start SOLIRIS
- stay up-to-date with all recommended vaccinations during treatment with SOLIRIS

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

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Commit to keeping track

As you begin treatment, take note of how you're feeling in your gMG Treatment Journal.



Be sure to track your symptoms over time. Make notes on any changes you see in your activities of daily living. **And don't forget to fill out an MG-ADL questionnaire every 3 months.**



Use those changes as motivation and for talking to your doctor at your next appointment.



Keep track of the medicines you take, including prescriptions, over-the-counter medicines, vitamins, and herbal supplements, as well as the vaccines you receive. Show this list to your doctor and pharmacist when you get a new medicine.

About Soliris® (eculizumab)

Understanding your medication



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

SELECT IMPORTANT SAFETY INFORMATION

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:
 - o chest pain
 - o trouble breathing or shortness of breath
 - o swelling of your face, tongue, or throat
 - o 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?” in the Medication Guide.

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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088.

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- Patients who responded to Soliris experienced improved gMG symptoms, usually by 12 weeks of starting treatment
- In a clinical trial of 125 patients, Soliris was shown to improve activities of daily living and muscle weakness in patients with unresolved symptoms, despite multiple treatments
- Clinical response in this trial was defined as:
 - ≥3-point improvement from baseline in MG-ADL total score at 26 weeks of treatment
 - ≥5-point improvement from baseline in quantitative MG (QMG) total score at 26 weeks of treatment
- Of patients receiving Soliris (n=62) or placebo (n=63)
 - MG-ADL: 60% reported an improvement in activities of daily living compared with 40% of those taking placebo
 - QMG: 45% had a clinically meaningful improvement in muscle weakness compared with 19% of those taking placebo
- The 14-day infusion schedule for Soliris was carefully studied when determining safety and efficacy. It’s important to follow your doctor’s prescribed treatment schedule and try to keep all of your infusion appointments within that 14-day time frame



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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.

Please see additional information on “What is the most important information I should know about Soliris?” on page 2.

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



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your day**

SOLIRIS®
(eculizumab)
Injection for Intravenous Use