

The first FDA-approved treatment for adults with **neuromyelitis optica spectrum disorder (NMOSD)** who are **anti-aquaporin-4 (AQP4) antibody positive**.

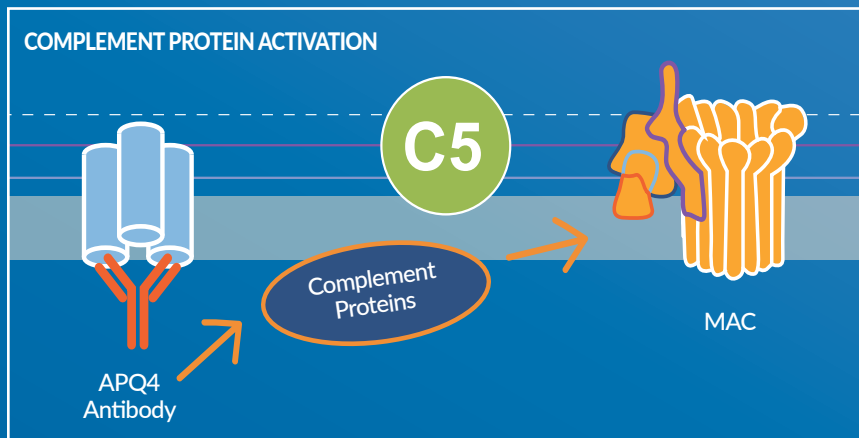
- The approval of SOLIRIS[®] for adults with anti-AQP4 antibody-positive NMOSD is based on comprehensive results from the Phase 3 PREVENT trial, which demonstrated safety and efficacy in prolonging the time to the first adjudicated on-trial relapse and reducing risk of attacks, also known as relapses, compared to placebo.
- SOLIRIS is a prescription medicine also FDA approved to treat other rare diseases:
 - patients with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH)
 - adults and children with a disease called atypical Hemolytic Uremic Syndrome (aHUS)
 - SOLIRIS is not for use in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
 - 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 PNH, or gMG, or NMOSD.



ABOUT ANTI-AQP4 ANTIBODY-POSITIVE NMOSD

In patients with anti-AQP4 antibody-positive NMOSD the body's own immune system can turn against itself to produce auto-antibodies against AQP4, a protein on certain cells in the eyes, brain and spinal cord, that is critical for the survival of those cells.

The complement system is a vital part of the immune system. It's comprised of multiple proteins that interact in a cascade-like fashion to destroy and eliminate microbes or cellular debris in response to infection or injury.²



- **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 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 two 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.



How SOLIRIS Works

SOLIRIS is a first-in-class complement inhibitor that works by selectively inhibiting activation of specific proteins in the complement system (C5a and C5b).¹

SOLIRIS interrupts the complement cascade by blocking terminal complement activation. By binding to complement protein C5, SOLIRIS blocks the formation of the membrane attack complex (MAC) [C5b] and complement-mediated inflammation (C5a).¹

The precise mechanism by which eculizumab exerts its therapeutic effect in NMOSD is unknown, but is presumed to involve inhibition of aquaporin-4-antibody induced terminal complement C5b-9 deposition.¹

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.

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Safety Profile

The most common side effects in people with NMOSD treated with SOLIRIS include: common cold; pain or swelling of the nose or throat; diarrhea; back pain; dizziness; flu-like symptoms including fever, headache, tiredness, cough, sore throat, and body aches; joint pain; throat irritation; bruising.¹



Recommended Vaccination

SOLIRIS increases your chance of getting serious and life-threatening meningococcal infections.

- Patients should be vaccinated according to current Advisory Committee on Immunization Practices (ACIP) guidelines to reduce the risk of serious infection.
- Patients should receive two weeks of antibiotics if SOLIRIS must be initiated immediately and vaccines were received less than two weeks before starting SOLIRIS therapy.
- Healthcare professionals who prescribe SOLIRIS must enroll in the SOLIRIS Risk Evaluation and Mitigation Strategy (REMS).



Established Efficacy

The efficacy of Soliris was established in the PREVENT trial, a randomized, double-blind, placebo-controlled trial that enrolled 143 patients with anti-AQP4 antibody-positive NMOSD (96 received SOLIRIS and 47 received placebo). In the PREVENT trial, the time to adjudicated on-trial relapse (primary endpoint) was significantly longer in adults who received SOLIRIS than those treated with placebo. SOLIRIS reduced the risk of relapse by 94% compared to placebo (hazard ratio 0.58; $p < 0.0001$).¹

At 48 weeks, 98 percent of patients receiving SOLIRIS were free of relapse compared to 63 percent of patients receiving placebo, per primary analysis.^{1,3}



SOLIRIS Dosing and Administration

SOLIRIS is administered only via intravenous infusion over 35 minutes. Patients receive 900 mg of SOLIRIS weekly for the first four weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter.

SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS, continued

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 the meningococcal vaccine and, if needed, get revaccinated with the meningococcal vaccine. Ask your doctor if you are not sure if you need to be revaccinated.

SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS, 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). 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.

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?”**

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
- 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.

Monitoring Disease After Stopping SOLIRIS

- **If you have PNH, your doctor will need to monitor you closely for at least 8 weeks after stopping SOLIRIS. Stopping treatment with SOLIRIS may cause breakdown of your red blood cells due to PNH.** Symptoms or problems that can happen due to red blood cell breakdown include:
 - drop in the number of your red blood cell count
 - drop in your platelet count

- confusion
- kidney problems
- blood clots
- difficulty breathing
- chest pain

- **If you have aHUS, your doctor will need to monitor you closely during and for at least 12 weeks after stopping treatment for signs of worsening aHUS symptoms or problems related to abnormal clotting (thrombotic microangiopathy).** Symptoms or problems that can happen with abnormal clotting may include:

- stroke
- confusion
- seizure
- chest pain (angina)
- difficulty breathing
- kidney problems
- swellings in arms or legs
- a drop in your platelet count

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?” in the Medication Guide.

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SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS, continued

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

- headache
- pain or swelling of your nose or throat (nasopharyngitis)
- back pain
- nausea

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

- headache
- diarrhea
- high blood pressure (hypertension)
- common cold (upper respiratory infection)
- stomach-area (abdominal) pain
- vomiting
- pain or swelling of your nose or throat (nasopharyngitis)
- low red blood cell count (anemia)
- cough
- swelling of legs or feet (peripheral edema)
- nausea
- urinary tract infections
- fever

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

- muscle and joint (musculoskeletal) pain

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

- common cold (upper respiratory infection)
- pain or swelling of your nose or throat (nasopharyngitis)
- diarrhea
- back pain
- dizziness
- flu like symptoms (influenza) including fever, headache, tiredness, cough, sore throat, and body aches
- joint pain (arthralgia)
- throat irritation (pharyngitis)
- bruising (contusion)

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.

For more information on SOLIRIS, please see full Prescribing information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections, also available at www.SOLIRIS.net.

1. SOLIRIS [package insert]. Boston, MA: Alexion Pharmaceuticals Inc.
2. Merle et al. Complement system part II: role in immunity. *Frontiers Immunol.* 2015; 6:257
3. Pittock SJ, et al. Trial of eculizumab in aquaporin-4 positive neuromyelitis optica spectrum disorder. *New England Journal of Medicine.* 2019

FOR ADDITIONAL INFORMATION, VISIT ALEXION.COM

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