

Meningococcal vaccination and Soliris® (eculizumab)

INDICATION

What is SOLIRIS?

SOLIRIS is a prescription medicine called a monoclonal antibody. SOLIRIS is used to treat:

- adults with a disease called neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive
- It is not known if SOLIRIS is safe and effective in children with NMOSD.

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.**
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.

You must get meningococcal vaccines at least 2 weeks prior to starting Soliris.

There are 2 types of meningococcal vaccines: MenACWY and MenB. Because each type protects against different types of meningococcus, you should receive both before starting treatment with Soliris and stay current with vaccination requirements.

Types	Dosing
MenACWY ^a	Administer 2 doses at least 2 months apart
MenB ^b	<i>Options based upon vaccine brand:</i> <ul style="list-style-type: none">• MenB-4C: 2 doses at least 1 month apart OR• MenB-FHbp: 3 doses (0, 1-2, and 6 months)^c

^aThe Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) guidelines recommend all adult patients undergoing complement inhibition receive the MenACWY booster every 5 years.

^bThe 2 types of MenB vaccines are not interchangeable. You must receive the same product for all doses.

^cFor MenB-FHbp, if dose 2 was administered at least 6 months after dose 1, dose 3 is not needed.

- The first meningococcal vaccination should occur 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
- Before you start Soliris, your doctor will reference the most up-to-date ACIP recommendations and prescribe medically appropriate vaccines according to his or her independent medical judgment

Talk to your doctor to learn more.

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

SOLIRIS[®]
(eculizumab)
Injection for Intravenous Use
300 mg/30 mL vial

SELECT IMPORTANT SAFETY INFORMATION (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.

SOLIRIS may also increase the risk of other types of serious infections. 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.

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.

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.

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